?ds

Set	Items	Description
S1	28911	HACCP
S2	10844133	MODEL OR SIMULATION
S3	7476099	SECURITY OR BIOSECURITY OR TERRORISM OR BIOTERRORISM OR (FOOD (W) (SAFETY OR SECURITY))
S4	8133476	FOOD
S5	12633890	FOOD OR VEGETABLE OR MEAT OR PRODUCE
S6	1858633	CONTAMIN? OR ANTHRAX OR BOTULISM OR SMALLPOX
S7	2241	S1 AND S2
S8	68168	S3 AND S5 AND S6
S9	839	S8 AND S7
S10	419525	(DISTRIBUTION OR SUPPLY)()CHAIN
S11	630	S1 AND S10
S12	102	S11 AND S2
S13	102	S12 AND S5
S14	80	RD (unique items)
S15	48	S14 AND S6
S16	48	RD (unique items)

3 of 8

Dialog Search
10 Aug 2004

Agri
Agribus
bio sci
foodregs
foodsci

?f s16 and py<2003
>>>File 10 processing for PY= : PY=2003
>>> started at PY=L??? stopped at PY=1961
Processing
Processed 10 of 56 files ...
Processing
>>>One or more prefixes are unsupported
>>> or undefined in one or more files.
Processing
Processed 20 of 56 files ...
Processing
Processing
Processed 30 of 56 files ...
Processing
Processed 40 of 56 files ...
Processing
Processed 50 of 56 files ...
Completed processing all files
48 S16
185573192 PY<2003
S17 33 S16 AND PY<2003
?t s17/medium,k/all
>>>KWIC option is not available in file(s): 19, 252, 399

17/K/1 (Item 1 from file: 98)
DIALOG(R)File 98:General Sci Abs/Full-Text

03760152 H.W. WILSON RECORD NUMBER: BGSI98010152 (USE FORMAT 7 FOR FULLTEXT)
Quantitative risk assessment: an emerging tool for emerging foodborne pathogens.
Lammerding, Anna M
Paoli, Greg M
Emerging Infectious Diseases (Emerging Infect Dis) v. 3 (Oct./Dec. '97) p. 483-7
SPECIAL FEATURES: bibl ISSN: 1080-6040
LANGUAGE: English
COUNTRY OF PUBLICATION: United States
WORD COUNT: 3453

(USE FORMAT 7 FOR FULLTEXT)

ABSTRACT: New challenges to the safety of the **food** supply require new strategies for evaluating and managing **food** safety risks. Changes in pathogens, **food** preparation, distribution, and consumption, and population immunity have the potential to adversely affect human health...

...a framework for predicting the impact of changes and trends on the

provision of safe **food** . Risk assessment models facilitate the evaluation of active or passive changes in how foods are...

TEXT:
... epidemiology of foodborne diseases is a result of complex interactions and changes in pathogens, foods, **food** distribution, **food** consumption, and population immunity (1-3). Predicting the impact of a trend in one part of the **food** continuum presupposes understanding of the whole system. Aspects of the **food** processing and distribution system can amplify or attenuate the trend as it grows into a potential health hazard. While a full understanding of pathogen **contamination** , infection, and survival is difficult, a systematic approach to assessing the impact of the pathogen...

...In hazard identification, an association between disease and the presence of a pathogen in a **food** is documented. The information may describe conditions under which the pathogen survives, grows, causes infection...

...used in exposure assessment, where the impact of processing, distribution, preparation, and consumption of the **food** are incorporated.

EXPOSURE ASSESSMENT
Exposure assessment describes the pathways through which a pathogen population is introduced, distributed, and challenged in the production, distribution, and consumption of **food** . This step differs from hazard identification in that it describes a particular **food** -processing pathway. Depending on the scope of the risk assessment, exposure assessment can begin with...

...the description of the pathogen population at subsequent steps (e.g., as input to a **food** -processing step). In any case, the intent of risk assessment is to track the pathogen...

...as the predominant paradigm for describing the public health consequences of human exposure to environmental **contaminants** (8). Within this paradigm, existing situations are measured and compared according to a measure of...

...It is now used proactively to support decisions such as selection of waste treatment technologies, **contaminated** site cleanup operations, and state and municipal priority setting for public health initiatives.
The shift...

...effectiveness of various regulatory programs is increasingly required on the basis of risk reduction. Microbial **food** safety, as a relative latecomer to the field of risk assessment, can take advantage of an emerging tool in the field of microbial **food** and water safety (9-12). Recognizing the deficiencies of current approaches to evaluating the risk for human illness from pathogens in **food** , the Council for Agricultural Science and Technology recommended that risk assessment provide the basis for establishing **food** safety priorities and policies (5). Because of recent initiatives advocating the widespread implementation of Hazard Analysis and Critical Control Points (**HACCP**) systems, quantitative risk assessment has been proposed as a means of providing health-outcome-based specification of microbial criteria for **HACCP** plans (12-14). Concurrently, international trade agreements have advocated that demonstration of increased domestic health...

...in a risk assessment) is the only acceptable basis for barriers to international trade in **food** (15-18). However, one of the most important benefits in the adoption of quantative risk assessment is improved understanding of the many factors that determine the safety of the **food** supply.

Some resistance to the adoption of risk assessment is likely. Good manufacturing practices and...
...on investment in producing a quantitative risk assessment may not be

high for an individual **food** company with a very conservative production process. However, good manufacturing practices and outbreak data are...

...particularly useful in predicting the impact of new products, newly recognized pathogens, and changes in **food** processing or in comparing international **food** systems. Whether changes in the **food** supply are planned (as in refocused inspection systems and minimally processed foods) or are occurring...

...is a place for all the data from diverse information gathering activities relevant to microbial **food** safety. Recent analyses of pasteurized liquid egg (19) and ground beef **contamination** (20) incorporated evidence from farm-based studies of pathogen prevalence, technology assessments comparing decontamination methods...

...designing the quantitative risk assessment process as an intelligent information bank, we can develop a **model** to accommodate the breadth of available information. The **model** provides a focus for discussions among workers from diverse disciplines: farmers, veterinarians, **food** -processing experts, microbiologists, and consumer behavior experts. The **model** also allows for consideration and comparison of control strategies for which experimentation would be very...

...of proposed research.

The most obvious users for quantitative risk assessment as applied to microbial **food** safety are agencies responsible for **food** inspection, disease surveillance, and **food** standards. These agencies have the most to gain from models that incorporate existing and new data, capture knowledge of the relevant features of the **food** processing and distribution continuum, and capture knowledge of the variability in consumer behavior and immune...

...to multidisciplinary discussion and best describes what is currently known and unknown. Without such a **model** , there is little common ground for the type of collaboration often advocated for addressing the...

...to support decisions regarding emerging foodborne diseases.

ESCHERICHIA COLI O157:H7 IN GROUND BEEF

A **model** of E. coli O157:H7 in ground beef has been developed to support comparative assessment of control strategies (20). The **model** describes the pathogen population from the production of ground beef (including carcass processing) to consumer cooking and consumption. The variability and uncertainty in the **model** are accommodated through the use of probabilistic representations for many of the parameters. To generate a representative distribution of risk, the **model** is simulated many times with different values selected from the probability distributions. This is a technique known as Monte Carlo **simulation** (20-22).

While the direct output of the **model** is a distribution of health risk from eating ground beef hamburger patties, a more important use of the **model** is to describe the changes in health risk associated with changes in various parameters. By...

...susceptible populations, we can study the impact of trends in disease risk factors. Because this **model** includes the farm-to-fork continuum, it is possible to assess the efficacy of interventions...

...of improved data at different points in the process can be estimated.

TOXOPLASMOSIS

A probabilistic **model** describing the incidence of toxoplasmosis was generated (23). While this **model** did not begin at the raw material level, valuable insights were gained in studying the...

...treated with certain drug therapies, the infection may have a smaller impact.

With such a **model** , the impact of varying risk factors can be

studied. Since the most serious consequences of...strategies (e.g., education and screening programs designed for pregnant women) can be compared to **food** -processing strategies intended to reduce overall exposure.

The **model** of T. gondii infection provides insight into the importance of detailed hazard identification to understand...

...assessment is the development of models describing the complex nature of pathogen populations in the **food** supply. Improved understanding of the efficacy of pathogen reduction is the most important side effect...

...a foodborne pathogen often include extensive documentation of pathogen levels at unconnected points in the **food** and consumer pathway. In contrast, a microbial risk assessment based on a **model** provides a repository of knowledge describing health risk outcomes and control strategies. The **model** improves with each new related study and each critical review as more and more relevant...
...Initially, models can be expected to be crude. However, as a base for discussion, a **model** can be very effective at soliciting input from experts in the **food** industry and the public health community. Input from epidemiologists, microbiologists, and industry safety managers can be merged into the **model** until it represents the best available understanding of the interacting features of the **food** supply and their effect on the distribution of health risk. Once the **model** has been developed, the impact of various control strategies and trends can be simulated. Our current inability to compare control strategies at different points of the **food supply chain** is evidence of the need for a system-level understanding that will improve decision-making...

...is no excuse for not making the best decision on the basis of available information. **Model** -based quantitative risk assessment can provide the decision-maker additional insights not typically evident in...

...not typically achieved by traditional approaches.

Many gains in decision support can be achieved through **model** -based risk assessment. Given that many current concerns are focused on emerging pathogens, it may...

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...

DESCRIPTORS:
Food -...

...Microbiology; Risk; **Food** industry
1997

17/K/2 (Item 1 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

3456541 Supplier Number: 03456541 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Critical control: as dairy processors implement more food safety measures, from HACCP to intervention technology, results are promising. (Special Report)
(Hazard Analysis & Critical Control Points reflect quality)
Dairy Field, v 185, n 5, p 42(4)
May 2002
DOCUMENT TYPE: Journal ISSN: 1055-0607 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 2764

(USE FORMAT 7 OR 9 FOR FULLTEXT)
Critical control: as dairy processors implement more food safety measures, from HACCP to intervention technology, results are promising. (Special Report)

TEXT:
Petrak, Lynn

When foodborne pathogens make headlines, **food** and beverage manufacturers often cringe at the thought of another product recall or, even worse... Such encouraging news reflects the success of farm-to-table efforts by the entire **food** chain, from farmers and producers to processors, distributors and end users. At the production level, the results underscore the importance of **food** safety programs.

The dairy industry has made **food** safety a priority for decades, if not close to a century. The Pasteurized Milk Ordinance...

...requirements for milk and dairy product processing, has been a positive example for the entire **food** chain. "Because of the PMO and state and federal oversight, milk products are one of the safest **food** categories today," says **food** safety consultant Donald Zink of Thousand Oaks, Calif.. Although there have been some devastating illness...

...consider the number of dairies in the U.S. and the volume of products they **produce** , the safety record is quiet remarkable."

The **HACCP** **Model**

While the PMO has ensured safety for dairy foods for years, other contemporary systems have emerged. Processors are increasingly formalizing voluntary Hazard Analysis and Critical Control Points (**HACCP**) programs, already mandated for **meat** and poultry plants, seafood operations and juice companies, for a variety of reasons.

HACCP is a science-based system that ensures **food** safety hazards are controlled to prevent unsafe **food** from reaching consumers. The system includes several basic principles, including an establishment of hazard analyses, critical control points, crucial limits, monitoring procedures, corrective actions, verification procedures and written documentation. **HACCP** also typically encompasses a prerequisite program, with such elements as Good Manufacturing Practices (GMPs) and Sanitation Standard Operating Procedures (SSOPs).

Zink believes **HACCP** programs are worthwhile, noting that the dairy industry has had similar systems in the past. "I think **HACCP** can bring some elements of **food** safety to dairy operations that the PMO does not address, particularly since dairies are beginning to look more like **food** processors as they become involved in more non-dairy products," he says. "However, under the PMO, dairies have long had an appreciation for **HACCP** principles such as the identification of critical control points, monitoring and verification."

Other industry leaders agree. "When you look at the whole setup with fluid milk, it is a **HACCP** **model** . The dairy industry has effectively lived with **HACCP** for a long time anyway," remarks Bill Haines, vice president of business to business marketing...

...Dairy Management Inc., Rosemont, Ill.

Indeed, because so many dairies have embraced the principles behind **HACCP** , it's easier for them to formalize the system. Northfield, Ill.-based Kraft Foods, for example, has long endorsed **HACCP** tools and techniques. "More than 10 years ago, Kraft Foods recognized that the principles of **HACCP** could enhance our **food** safety programs, and we incorporated **HACCP** -based systems in all our manufacturing facilities, including our dairy facilities," recalls Joe Meyer, manager...

...According to Meyer, the system works best when it is a synergistic effort. "We view **HACCP** as the top of our **food** safety program's pyramid. In order for **HACCP** to be successful, we need a strong base of general GMPs, such as training, equipment...

...to name a few."

Kraft was one of the first manufacturers to join a voluntary **HACCP** pilot program established in 1999 by the National Conference of Interstate Milk Shipments (NCIMS), the...

...D.C.-based International Dairy Foods Association (IDFA), is a key player on the NCIMS **HACCP** committee and strong proponent of a voluntary **HACCP** program. "If you're a dairy processor and have to have different **HACCP** programs for larger customers and for private label (customers), it makes sense to have one comprehensive program to meet all your needs," he says, adding that **HACCP** in effect replaces the requirements under the PMO. It also may make business sense as well. "What I'm hearing from a number of people is that **HACCP** is an economical benefit as well. It means better

efficiency, less production loss. All of...

...quality control manager Rebecca Piston, the program has been successful. "We have a living, breathing **HACCP** plan as opposed to one sitting on a shelf, and our customers appreciate that," she...

...developed several supporting programs. One of the most significant efforts has been a new IDFA **HACCP** Certification Program, which the association launched in January. The program, available for individuals as well as company teams, aims to provide a "one-stop" **HACCP** training and certification program, including workshops, training manuals and audits. "One of the things we knew was that processors are already doing **HACCP** in one fashion or another. What we are trying to do with the **HACCP** certification program is to provide a comprehensive **food** safety program," explains Sayler.

A major factor behind IDFA's decision to offer a certification program was the decision by the **Food** and Drug Administration (FDA) to mandate **HACCP** compliance for juice manufacturers. In January 2002, large juice plants (defined as companies with more than 500 employees) were required to have a full **HACCP** program in place; small and very small plants will follow in 2003 and 2004.

Many...s juice ruling. "Up to 60 percent of our membership also produces juice, and dairies **produce** about 30 percent of orange juice from concentrate," points out Sayler. "Because of the juice...

...this is a great time to launch the certification program."

Due to the number of **HACCP** queries, especially from dairies that also **produce** juice, IDFA launched a new Web site in April, www.IDFAhaccp.com. Geared toward the dairy and juice industry in light of the new requirements, the site supports the IDFA **HACCP** certification program and provides news updates and additional resources.

The new Web site can be used to learn more about the NCIMS **HACCP** program. The process, says Sayler, is fairly simple. A dairy company contacts JDFA or its...

...an application. Once the application is reviewed and accepted by the NCIMS committee, training begins. **HACCP** plans are then written, followed by review and in-plant listings by state regulators. The...

...takes from two months to six months, according to Sayler.

Proponents of the system believe **HACCP** works for all kinds of dairy operations because it adapts to changing **food** safety environments. "The beauty of **HACCP** is the number of ways it can be applied. It really allows you to focus...

...the checklist is the same in every plant, every state. It was not flexible, like **HACCP** is."

Other **Food** Safety Measures and Matters

HACCP continues to be an industry focus, but several additional measures that may or may not...

...is also a confidence booster for plants and customers.

Lee-Ann Jaykus, associate professor of **food** safety at North Carolina University in Raleigh, N.C., has conducted several research projects in...

...less. While Jaykus and her team are currently using non-fat dried milk as a **model** , they're hoping to expand their work. "We tried to use a simple **model** and are in the process of applying it to more complicated products, like yogurts and cheeses," she says.

Sanitation is another major issue that falls within **HACCP** parameters. Among other concerns, **HACCP** standards require dairies to determine pest

contamination and infestation. Orkin Exterminating Company, Atlanta, Ga., helps **food** and beverage manufacturers comply with **HACCP** and other types of government regulations with a host of integrated pest management programs. Orkin...

...weekly or biweekly basis.
According to Orkin's director of commercial quality control, Zia Siddiqi, **food** processing facilities are especially vulnerable to pest infestations because of round-the-clock schedules and...

...lights, or the installation of pest and rodent monitoring devices.
Because of the nature of **food** plants, repellents are not a priority. "I don't want to put a lot of...

...in a plant). You put chemicals in as a last resort," he says.

Siddiqi believes **food** companies are more proactive than ever before in terms of ensuring quality and safety. "I...

...the six o'clock news. And no one wants that."

A Current Perspective

Although voluntary **food** safety measures are having a direct impact on foodborne illness outbreaks, another issue is looming...

...months where it hasn't been brought up."
According to Haines, bioterrorist threats on the **food** supply are uncertain, but vulnerabilities exist. "The problem is you have to monitor the whole **supply chain** . This is an insidious problem -- when you start talking about bioterrorism, you start talking about in the region to help them with their **HACCP** programs, and senses the change. "I've been hearing more questions about biosecurity," she says...

...immediate and long-term future, processors are pragmatic about the importance of their commitment to **food** safety. " **HACCP** is an excellent tool for building science-based **food** safety systems, but each situation needs to be evaluated individually to determine if **HACCP** is the best tool for that situation," says Meyer of Kraft. "While **HACCP** is a very important part of a **food** safety system, a number of other effective tools exist, such as sanitation, environmental testing, equipment design and training."

RELATED ARTICLE: **HACCP** : Good for Business?

Structured **HACCP** (Hazard Analysis and Critical Control Points) plans and implementation clearly require extra effort and expense. While some **food** manufacturers recognize the benefits of such a system, they have also privately grumbled about the cost and time involved.
One management consultant for the **food** industry says that despite upfront work, **HACCP** plans ultimately benefit the processor. According to Brian Collis, principal of Collis Consulting Inc. of...

...of PMI Management of Barrington, Ill., the dairy industry is at a pivotal area regarding **HACCP** .

"With dairy, it's moved and evolved," he says, noting that processors are reacting to continual consumer surveys which show an interest in **food** safety assurance programs. "If you step back and look at the mechanics of it, it is actually a customer-driven program. We have a sophisticated consumer base out there and **food** safety is number one -- this is one way to scaffold a better business relationship with...

...those in the dairy industry in Canada and the United States, Collis reminds them why **HACCP** works well for all parties. He has even published a paper called, "What You Should Know About **HACCP** ," in which he shares three compelling business reasons why **HACCP** makes smart business sense:

Some excerpts:

* Business Reason #1: Your customers! They are demanding and sophisticated and they expect **food** to be nutritious and safe to eat. **Food** safety is their number one concern. Remarkably, in this age of modern technology and strict government regulations, the cost of **food** -borne illnesses to Americans are second only to AIDS in terms of lives lost and money spent. (1) The Center for Disease Control and Prevention estimates that **food** borne illnesses cause as many as 325,000 serious illnesses and 5,000 deaths each...

...real people who may very well be your customers. Having a well-developed and implemented **HACCP** system demonstrates your commitment to providing your customers with product of the highest possible standard.

* Business Reason #2: Cost-savings! **HACCP** establishes preventative measures to prevent, eliminate or reduce potential hazards from entering the product. **HACCP** allows you to manage the risk as part of an on-going process. Compare this...

...what cost? What are the economic consequences of a warehouse full of defective, unsaliable product?

HACCP is a cost- effective strategy that reduces the business risks associated with product rework, product...
...all reasonable care" was taken to protect the consumer. A well-designed, implemented and maintained **HACCP** system will support the position that all reasonable care and precautions have been taken protect to the consumer. A critical success factor of **HACCP** is record keeping. Records demonstrate that all appropriate measures were taken to manage **food** safely and protect the consumer.

Brian Collis can be contacted at (204) 487-3700, fax...

INDUSTRY NAMES: **Food**
PRODUCT NAMES: **Food** and kindred products (200000)

17/K/3 (Item 2 from file: 9)
DIALOG(R)File 9:Business & Industry(R)
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2312249 Supplier Number: 02312249 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Improved distribution testing, tightened distribution system in food **packaging forecast by Marsh at FuturePak**
(Of all take-out food **purchases, home meal replacements represent 37% and may rise 10%/yr through 2005)**
Food Chemical News, v 40, n 40, p 5+
November 23, 1998
DOCUMENT TYPE: Newsletter ISSN: 0015-6337 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 2024

(USE FORMAT 7 OR 9 FOR FULLTEXT)
Improved distribution testing, tightened distribution system in food **packaging forecast by Marsh at FuturePak**
(Of all take-out food **purchases, home meal replacements represent 37% and may rise 10%/yr through 2005)**

ABSTRACT:
Tony Ponder of Eastman Chemical has announced a new class of polyethylene plastomers for packaging **food** . These plastomers offer super stiffness, cold temperature strength and super heat resistance. Applications include stand...

...dollars spent on foods, about 50% go to take-out foods. Of all take-out **food** purchases, home meal replacements represent 37% and may rise 10%/yr through 2005. Case-ready...

TEXT:

Improved distribution testing of packaging materials and a tightened distribution system will allow **food** packaging to contribute mightily to world **food** security system strategies to defeat hunger by the year 2015, Kenneth Marsh, Cryovac Chair in...

...vibration indicators, abuse indicators, toxin sensors and microorganism sensors.

One of these applications, the SIRA **Food** Sentinel System, which tracks pathogen microorganisms in **food** utilizing an enhanced bar code format, was described to the conference by Douglas Park, Louisiana...

...of packaging for different markets, and postponement of packaging to near the end of the **distribution chain** to save transportation dollars.

EU-U.S. differences noted

Packaging materials that are better able...

...of packaging suppliers described new or improved materials aimed at better meeting the needs of **food** packagers.

Some of these new materials unintentionally illustrated the differences in U.S. and European Union packaging regulations.

For example, the stealth scavenging system developed by Cryovac (See **Food** Chemical News, Nov. 16, Page 9) is cleared in the U.S. but is not...

...polymer recently introduced by Shell Chemical Co., poly(trimethylene terephthalate) (PTT), can be used for **food** packaging in Europe because it is included in the list, but faces regulatory hurdles in the U.S.

In fact, Shell's Barry Cristea and Charles Hwo indicated that **food** packaging use in the U.S. will be dependent on whether there is enough market interest for the firm to pursue approval as an indirect **food** additive. Cristea reported that the firm has initiated discussions with FDA about just what is...

...Tony Ponder announced publicly for the first time a new class of polyethylene plastomers for **food** packaging -- MXSTEN CV plastomers -- which, he said, are getting FDA approval for **food** cooking applications. The new plastomers, Ponder said, have super sealability and hot tack window, super...

...their laminations meet the need of various regulations." CUR222 films are also approved for direct **food** contact in German and EU regulations, Reich noted.

Achieving unseen curing speeds for **food** -approved laminates is now possible with CUR222 lamination films, Reich said, adding that CUR222 films ...

...firm meets or exceeds performance attributes of current home meal replacement packaging in terms of **food** safety, microwavability, insulative property, tight lid seals, rigidity, attractiveness and cost.

To illustrate the size...

...take-out foods and that home meal replacements currently represent 37% of all take-out **food** purchases and are expected to grow at 10% annually through 2005.

Case-ready retail packaging...
...Gorlich, World Class Packaging Systems, who noted that supermarkets "who want to safely sell fresh **food** products like a can of peas" are demanding totally sealed case-ready retail packaging.

Supermarkets don't want any butchery or **food** preparation to occur at the supermarket level anymore, Gorlich said, and also do not "want...

...liability that is associated with in-store preparation and the packaging of potentially tainted raw **food** products like fresh meats that were previously delivered to the supermarket in bulk for in...

...gas mix and a shelf-life test, installation of the system, and development of a **HACCP** plan, including sanitation of the packaging machinery.

Two vital areas for potential cross **contamination** that are emphasized by his firm, Gorlich said, are the tooling and gas surge tank...

...that the tooling area be immediately cleaned and sanitized to prevent any growth or cross **contamination** from bacteria when a package jams in the tooling and some **food** product becomes lodged within the mechanism, he said.
Additionally, he said, "If the surge tank is not cleaned and sanitized properly any **contamination** in the tank at the time of packaging will be blown directly back into every...

...retort and has a faster recovery of oxygen permeability in multi-layer films.

A working **model** for prediction of gas barrier in biaxially oriented semi-crystalline polymers and for polymers containing...

...industrial chemicals, and fertilizers.

Uses of biaxially oriented nylon film include natural cheese wrappers, frozen **food** packaging, bag-in-box, coffee packaging, modified atmosphere packaging and shelf-stable pouches replacing No of potential uses, including **food** packaging uses.

Kent Bryant, DuPont, noted that advances in temperature-resistant acid copolymers for cook-in applications "are enabling the **meat** packaging industry to move to higher cook-in temperatures and shorter cycle time while ensuring...

17/K/4 (Item 3 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

2155009 Supplier Number: 02155009 (USE FORMAT 7 OR 9 FOR FULLTEXT)
HMRs challenge manufacturers
(Takeout food orders surpassed restaurant dining for the first time in 1996, and new and existing technologies are currently rising to meet the growing consumer demand for home meal replacements)
Food Engineering, v 70, n 5, p 67+
May 1998
DOCUMENT TYPE: Journal ISSN: 0193-323X (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 2529

(USE FORMAT 7 OR 9 FOR FULLTEXT)
(Takeout food orders surpassed restaurant dining for the first time in 1996, and new and existing technologies...
)

ABSTRACT:
...demand. According to the Mealtime Trends study conducted by the NPD Group (Rosemont, IL) for **Food** Marketing Institute, takeout orders surpassed restaurant dining for the first time in 1996. For several years supermarkets have been trying to grab a bigger share of the fast **food** market by expanding their prepared **food** offerings. This led to such approaches as in-store **food** preparation to in-house or third-party commissaries to purchasing packaged HMRs and their components...

TEXT:

...demand. According to the Mealtime Trends study conducted by the NPD Group (Rosemont, IL) for **Food** Marketing Institute, takeout orders surpassed restaurant dining for the first time in 1996.

Supermarkets have...

...several years -- with varying degrees of success -- to snag a bigger share of the fast- **food** market by expanding their prepared **food** offerings. This bred alternative approaches ranging from in-store preparation to in-house or third...

...success to supply fresh refrigerated foods for the HMR market. During the 1980s, several major **food** processors launched refrigerated fresh **food** products which failed in the marketplace, noted Edward E. DeLuca, a former Kentucky Fried Chicken...

...as 36 degrees F, and 41 degrees F (the target cited by both the FDA **Model Food** Code and the UK Chilled Foods Association for refrigerated distribution).
DeLuca expressed three concerns about...

...the technologies which make possible manufacturing and distributing safe, refrigerated ready meals. In addition to **HACCP** (Hazard Analysis Critical Control Points) and its prerequisite SSOPs (Safe Standard Operating Procedures), successful HMR...

...clean-room packaging, modified atmosphere packaging (MAP) and product-control solutions to manage the perishable **supply chain** from raw materials through point of sale.

A centralized cold-chain management system developed by...

...data but not much information." For manufacturers shipping hundreds of truckloads per day, the recorders **produce** reams of stripcharts that are bulky, difficult to handle and require many hours to read...in active films which control metabolic rates to help preserve the natural immunosystem of each **vegetable** ; a bakery package with an inside active membrane which repels moisture, retaining flavors and aroma...

...are hot-filled into barrier-plastic casings, then tumble-chilled; solid foods such as whole- **meat** products are vacuum-packaged in plastic casings, then immersion-cooked and chilled in an automated cook tank. The system allows **food** processors, commissaries and institutional kitchens to build an inventory of prepared foods which can be reheated and served to meet consumer demand.

Mallard **Food** Products (Modesto, CA), acquired last August by Tyson Foods (Springdale, AR), combines cook/chill for **meat** entrees with a proprietary process to extend shelf life of starch items (such as mashed potatoes and rice) to **produce** its 13-item line of Cooking Made Easy refrigerated HMR kits. Refrigerated shelf life is...

...and "intertwining with their R&D people" to assure quality and safety programs such as **HACCP** , said President Rod A. Harris at the Summit.
Harry's operates a cook/chill process...

...far away as Chicago and Washington, DC.

Clean-room sanitation

One of the few US **food** processors operating a clean room with MAP packaging is Celantano (Verona, NJ), the frozen Italian **food** processor which launched its Real Meals line of fresh refrigerated HMRs in 1996.
Celantano's...

...material preparation and secondary-packaging areas are segregated from processing and packaging to prevent cross- **contamination** .

Celantano produces more than 30 different HMR **meat** and pasta-based

entrees plus side dishes totaling more than 100 SKUs, President Domenick Celantano Jr. told **Food** Engineering. Products are MAP-packaged in banded-label CPET (crystallized polyethylene terephthalate) barrier containers from...

...in Claremont, NC, operates a clean room for MAP-packaging refrigerated HMR products for the **Food** Lion supermarket chain. The products are packaged in Therma-Tuff dual-ovenable CPET barrier trays...

...Piscataway, NJ).

Cook/Chill Grows With HMR Trend

Cook/chill applications have been growing among **food** processors, supermarket chains and institutional foodservice operators along with the demand for fresh, refrigerated prepared foods.
Buehler **Food** Markets, a 10-store supermarket chain expanded its kitchen facility at Wooster, OH to a...circulates through the heat exchanger and is returned to the ice builder.

* A boiler to **produce** steam for heating the kettles and cook tank.

Buehler uses its cook/chill system to...

...Logistic issues

* Cost of product

* Limited variety

Out-source/joint venture/lease to restaurant/ fast- **food** chain

Positives

* Brand recognition

* Operational expertise
* Low cost

Negatives

* Lack of control

* Does little for...

INDUSTRY NAMES: **Food**

17/K/5 (Item 4 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

2107272 Supplier Number: 02107272 (USE FORMAT 7 OR 9 FOR FULLTEXT)
1998 Survey of food **manufacturing trends: A clear direction**
(Top trends in food **manufacturing in 1998 are presented)**
Food Engineering, v 70, n 3, p 77+
March 1998
DOCUMENT TYPE: Journal ISSN: 0193-323X (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 2704

(USE FORMAT 7 OR 9 FOR FULLTEXT)
1998 Survey of food **manufacturing trends: A clear direction**
(Top trends in food **manufacturing in 1998 are presented)**

ABSTRACT:
The top 23 trends in **food** manufacturing in 1998 are presented based on a survey of 201 executives and operations people by ' **Food** Engineering.' The top 10 trends are automation/information/integration, new

products/processes/technologies, process flexibility/efficiency/productivity, **HACCP / food** safety/compliance, outsourcing/co-packing, teams/training issues, new/improved packaging, alliances/partnerships, acquisition/consolidation...

TEXT:

FOOD ENGINEERING'S 1998 TRENDS SURVEY REVEALS CONFIDENCE IN THE MANUFACTURING MISSION.

CHARLES E. MORRIS, MIDWEST EDITOR

Food Engineering's 1998 Manufacturing Trends survey reveals few surprises. But most respondents to this year's survey seem to know exactly where they're going as **food** manufacturing heads into the 21st century.

Top management in a few instances many lack vision...

...process control (SPC)	2.4	1.9
On-line analysis	2.4	2
Process modeling/ **simulation**	1.9	1.5
Fewer, bigger plants	2	1.8
HACCP	2.6	2.2
ISO 9000	1.9	1.6
Continuous replenishment (CRP)	2	1.7
Supply - chain integration	2.2	1.8
Cross-docking	1.8	1.5
TQM:		
Self-managing teams...		

...Moderate priority = 2, High priority = 3
Scores indicate mean or midpoint of panelist ratings
(Source: **Food** Engineering 1998 Manufacturing Survey)

Veteran panel

This year, **Food** Engineering expanded it's annual Manufacturing Survey beyond our Executive Advisory Panel to include additional...

...respondents this year, 90 (45 percent) have more than 20 years of experience in the **food** industry; 72 (36 percent) have 10 to 19 years experience; 27 (13 percent) have five...

...in priority over the next five years (see graph on page 78).

Last year, on **Food** Engineering's 0 to 3 scale, only a few of these trends were seen as...
...0 "moderate priority" score toward the "high priority" range by 2003.

Our respondents predict that **HACCP** (Hazard Analysis Critical Control Points) and flexible manufacturing -- not surprisingly -- will surge furthest ahead in priority over the next five years. **HACCP** is now mandatory in the **meat** , poultry and seafood industries, and will soon be mandated for fruit/ **vegetable** juices and eggs as well. "We are rebuilding our facility with **HACCP** in mind," reports a turkey products plant manager. "The **food** safety issue is driving the shape of our manufacturing operation."

But many manufacturers are nevertheless implementing **HACCP** where it is not required: Of 146 respondents from industry segments where **HACCP** is not mandated, 72 percent report **HACCP** fully implemented, partially implemented or planned -- and 34 percent have fully implemented it! " **HACCP** (is) the ISO 9000 of the **food** industry," says the plant engineer at a manufacturer of dry soups and gravy bases.

On...

...a Midwestern confectionery plant responded: "SPC" and "teams." The senior development engineer at a Southern **meat** casings plant answers:

"Online instrumentation for faster response (and) better record keeping."

Estimated Percentage of...

...7
500 or more 32.4 40.9
* Mean estimate for each location category
(Source: **Food** Engineering 1998 Manufacturing Survey)
Continuing the trend of recent years, large and mid-size **food** companies continue to outsources more engineering work as they add projects and/or reduce internal...or toll manufacturing, due to its high impact on output."

As shown on table below, **food** processors continue to outsource engineering services at a growing rate, and -- for the first time since **Food** Engineering started tracking this trend several years ago -- the percentage of engineering work outsourced by small **food** companies (less than 100 employees) is growing as opposed to the percentage of engineering work...

...s ratings closely parallel last year's results. In the wake of last year's **meat** **contamination** crises and FDA's December 3 final rule on irradiation of red meats, however, 27...

...50 27
Magnetic resonance imaging 22 35 43
Predictive process control 44 44 12
(Source: **Food** Engineering 1998 Manufacturing Survey)

This year, we added predictive process control to the list. As...

...high potential -- in spite of the fact that few applications exist to date in the **food** industry. Probable reason: Every industry segment applies computerized process control, so the advantages of predictive...

...panelists responded with 110 answers, most interrelating several trends and sounding variations on common themes.

Food Engineering compiled these into a Ten Top Trends list (see table on page 77), which varies somewhat from last years top ten because of these interrelationships. **Supply** - **chain** management, for example, ranked third last year but integrates this year with flexible manufacturing, partnerships...
...manufacturing competencies 22.9
Greater engineering efficiency 24.9
Greater manufacturing efficiency 50.2
(Source: **Food** Engineering 1998 Manufacturing Survey)

New products, processes and manufacturing technologies rank together as the second...we will get into extrusion of cereals," adds the purchasing director at a cereal breakfast **food** company. "(We're) going from batch to continuous processing," states the vice president of a...

...market demands is the third major trend cited by our respondents. Several relate flexibility to **supply** - **chain** management and Efficient Consumer Response (ECR). "Continuous replenishment (CRP)," says the vice president/general manager...

...a Northwest canning plant. "There's not much opportunity for growth in the current canned **vegetable** segment."

Several respondents see workforce and training issues having a major impact. "Ill equipped (and...
...Quality control 46
Packaging 38
* Totals more than 201 due to multiple responsibilities
Industry Segment(*)

Meat /poultry		48
Bakery		52
Dairy		31
Flavors/ingredients		48
Canned fruit/veg/entrees		25
Fats...		
...grain	41	
Beverage		50
Other		49

* Totals more than 201 due to multiple products
(Source: **Food** Engineering 1998 Manufacturing Survey)

Alliances and partnerships wild have major impact but in varying ways. A process engineer at a Texas **meat** plant predicts that "partnerships will be critical to survival in the next century," while the vice president/manufacturing at a Pennsylvania snack **food** producer foresees "fewer vendor partners." The purchasing manager at a major Northwest **vegetable** processor sees " **supply** - **chain** management" coupled with "supplier alliances and partnership" as offering "excellent cost-reduction opportunities."

Ten Top **Food** Manufacturing Trends

1. Automation/information/integration

2. New products/processes/technologies

3. Process flexibility/efficiency/productivity

4. **HACCP** / **food** safety/compliance

5. Outsourcing/co-packing

6. Teams/training issues

7. New/improved packaging

8. Alliances/partnerships
9. Acquisition/consolidation

10. Improved maintenance

(Source: **Food** Engineering 1998 Manufacturing Survey)

' **Food** Plants of the Future'

They'll incorporate **HACCP** , flexibility, new technologies...and be located in faraway places!

The October '97 edition of the newsletter FB&CP News, published by the **Food** , Beverage & Consumer Products unit of Fluor Daniel, Inc., presents Fluor Daniels vision of **Food** Plants Of The Future." Following are some excerpts:

* They will be governed by **HACCP** plans, which will involve designing for sanitary operations and to prevent hazards from occurring in...

...as flooring brick are often hard to find, so epoxy coatings will be more common.
* **Food** plants in developing countries will be "light-sized" to fit underdeveloped transportation systems and thus...

...convenient processed foods. Such foods will also boost developing economies by improving health and reducing **food** preparation time for women. ...

INDUSTRY NAMES: **Food**

PRODUCT NAMES: **Food** and kindred products (200000)

17/K/6 (Item 1 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

09426112 Supplier Number: 82670709 (USE FORMAT 7 FOR FULLTEXT)
Meeting the challenge: Food safety and globalization: As food suppliers and retailers extend their global reach, concerns for food safety continue to grow.
Radice, Carol
Grocery Headquarters, v68, n1, p30(4)
Jan, 2002
Language: English Record Type: Fulltext
Document Type: Magazine/Journal; Trade
Word Count: 2675

(USE FORMAT 7 FOR FULLTEXT)
Meeting the challenge: Food safety and globalization: As food suppliers and retailers extend their global reach, concerns for food safety continue to grow.
TEXT:
...and-mouth disease and Mad Cow Disease, have caused many grocery retailers to examine their **food** safety methods and take stock of the fact that globalization can also have its downside.
... something far more unexpected -- the need for standards to address growing concerns of bioterrorism and **food** safety. The solutions for which, observers believe, will likely emanate from total **supply chain** responsibility.
Getting businesses worldwide on the same page by creating global-based standards is crucial...

...it includes. They must also include determining the measure the industry employs to protect the **food** supply as well as the technology utilized to trade products through the **supply chain** . The Global **Food** Safety Initiative (GFSI), a cooperative project of FMI and CIES, and the technology-based Global...

...for Washington, D.C.-based Grocery Manufacturers Association. "Despite the events of September 11, the **food** industry remains committed to global growth. For several years, GCI has been working toward setting...

...The landscape has become much more global and issues around the globe now impact the **food** industry in a very significant way," says Geoff Wissman, vice president of Columbus, Ohio-based...

...category definitions, brand development, and technology to track movement and even how to comply with **food** safety needs. In order for manufacturers and retailers to transact across borders, they will need to figure out what standards are needed and what are not."
The issue of **food** safety in a global world was the focus of a recent World Health Organization (WHO) report, **Food** Safety -- An Essential Public Health Issue for the New Millenium. In the report, WHO director general Gro Harlem Brundtland, based in Geneva, Switzerland, discussed the global seriousness of **food** safety. "In recent years, a number of extremely serious outbreaks of foodhorne disease have occurred...

...continent, demonstrating both the public health and social significance of foodborne disease. The intensification of **food** production and the consolidation of the **food** industries present opportunities for foodborne pathogens to infect large numbers of consumers."
The United Nations' **Food** and Agriculture Organization (FAO), based in Rome, Italy, and WHO have issued a joint call for countries to develop and apply international **food** safety and quality standards to protect health and trade and restore consumer confidence. Both groups say issues such as intensive rearing of **food** , crops and animals, coupled with a large population of at-risk people (the elderly, the...

...greater reliance on reheated foods and meals eaten out are all contributing factors to increased **food** safety concerns. "This global marketplace offers opportunities to buy and sell at the best commercial...
...but it also means a greater challenge for the safer sourcing, preparation and selling of **food** ," Brundtland adds.

In addition to concerns of unintentional tainting of **food** , the events of September 11 have created new concerns of the world's **food** supply becoming intentionally **contaminated** . Most government officials say these concerns are not likely to come to light, but at...

...Monies are being appropriated to help the government agencies responsible for inspecting the country's **food** supply ...the table would give the government power to seize or recall tainted products and inspect **food** manufacturers procedures and records.

Despite these efforts, industry observers are wondering whether retailers will alter...

...2000. As of October, the group consisted of more than 40 retailers, representing 65% of **food** retail revenue worldwide, that have joined together with key manufacturers including Nestle, Sara Lee, Unilever, Kraft, Coca Cola and General Mills to take a leadership role in maximizing global **food** safety.

Cees van der Hoeven, president of Netherlands-based Ahold, a member company on the...
...areas including developing benchmark safety standards, creating a rapid alert system, promoting consumer education on **food** handling and encouraging worldwide government support. In a keynote speech at the World **Food** Business Forum in Prague last June, Van der Hoeven said, " **Food** is safer than ever and we cannot accept that **food** items, rightly or wrongly, are perceived as unsafe. We cannot leave **food** safety only in the hands of governments even though they historically ensured through legislation and controls that **food** was produced in safe way."

He adds that the industry--from government agencies to retailers...

...work together to improve consumer confidence. Van der Hoeven said the task force developed a **food** safety benchmark standard against which existing standards can be checked and validated. "Fewer, but stricter...

...most from this is the consumer, whom we now provide with a global norm in **food** safety."

The standards cover quality management systems, good practices in agriculture, manufacturing and distribution and a Hazard Analysis and Critical Control Points (**HACCP**) implementation. Van der Hoeven says the task force has developed a series of protocols for...

...A key component of the initiative is the development of an early warning system. "Traditionally **food** reaches the consumer before sufficient information is available to make a **food** safety decision," he says. "Our industry has agreed to improve the speed and effectiveness of our response to **food** safety crises. We are running a pilot project to test the effectiveness of using the Internet as a means to exchange **food** safety information."

Van der Hoeven placed particular onus on international governments and cited the FDA...

...the world should not be an excuse to exclude a region or country from the **food** safety initiative," he says. "One of the main challenges for government, especially Europe, is the need to reform agriculture policy. To maximize **food** safety, the European Commission and national governments have to eliminate structural overcapacity in the agricultural...

...costs, and ensure tracking and tracing. We respect the role of the FDA to secure **food** safety, and we see nothing wrong in Europe emulating all the good things the FDA represents."

Ahold's Albert Heijn supermarkets have begun taking measures to implement **food** safety standards under the initiative. "We consider **food** safety as part of a larger pyramid of quality, one which requires a clear strategy," stated Simone Hertzberger, vice president, quality assurance at Albert Heijn, at CIES International **Food** Safety Conference in Geneva last

September. "To this end we have focused on four key areas: agreements with suppliers, **supply chain** influencing and traceability, use of **HACCP** throughout our operations and communicating this message to our customers."

While agreeing with the initiative...

...and all pre-farm or primary products by the beginning of 2003.

The debate concerning **food** safety and the measures necessary for change will no doubt continue for some time, but...

...necessary part of a changing world, according to Larry Busch, director of the Institute for **Food** and Agricultural Standards, director of Partnerships for **Food** Industry Development--Fruits & Vegetables and professor at Michigan University in East Lansing. "The length of the **supply chain** today which now carries global ramifications has increased the places where a problem may emerge...

...is necessary, he also sees it as a challenge. "This will require everyone in the **supply chain** to buy into this from producers and distributors to brokers and supermarkets. In the past, coordination of any type of **supply chain** effort, particularly with **produce** , has traditionally been weak. The one thing the industry needs to recognize is the danger in promoting **food** as totally safe. You can strive toward having safer products, but there is no such thing as the perfectly safe **food** supply and there never will be."

TOP 10 RETAILERS WORDWIDE

1 Wal-Mart Stores USA...

...Target USA

Source: Top 100 Retailers Worldwide 2000 Report, Retail onward

RELATED ARTICLE: THE IRISH **FOOD** SAFETY EXPERIENCE

The Irish have moved to the forefront of the **food** safety issue. Among the discussion of **food** safety at the Global **Food** Safety Initiative (GFSI), CIES International **Food** Safety Conference in Geneva this past September were case studies of countries who designed aggressive **food** safety programs. Not surprisingly, Ireland was touted as "a **model** of effective coordinated action by regulators and companies over **food** safety."

Patrick Wall, chief executive of the **Food** Safety Authority of Ireland (FSAI), knows the formula for success. "Partnerships pay. Cooperation has been...

...key influence to cope with the scientific uncertainty and political conflict, which are part of **food** safety," he says, adding that the FSAI was created as an independent agency responsible for coordinating government regulations and its primary objective is to develop partnerships with **food** companies to achieve a seamless chain and raise consumer **food** safety awareness.

Building trust has been a key goal of the agency. "Implementing change isn...

...at every stage helped us avoid a false sense of security as a result of **HACCP** implementation."

Ireland's largest chicken producer, Carton Brothers, has been working with FSAI and Dublin...

...to Vince Carton, managing director of Carton Brothers in Dublin, the company has engaged in **HACCP** and biosecurity training for workers at the farm level as well as stepped up vet...

...which we raise the poultry and what we feed them to include a hormone-free, **vegetable** diet and exclude GMO content in response to recent consumer concerns," he says. "Technology is...

...a point of difference in the shopper's mind."

Superquinn has a history of making **food** safety a top priority. Paula Mee, **food** and nutrition manager for the chain, says the decision to enhance **food** safety was al logical one given that about 80% of the chain's business comes from sales of fresh **food** . The chain has developed a DNA tracing system for beef and has established its own...

...on communicating this message to consumers as to what we are doing to protect their **food** with the idea that unless we tell them the measures we take to ensure their...

...Superquinn also focuses on educating store and management personnel. All store-level staff receive fresh **food** training and weekly operations meeting open with a **food** safety update.
INDUSTRY NAMES: BUSN (Any type of business); **FOOD** (**Food** , Beverages and Nutrition)
20020101

17/K/7 (Item 2 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

09193967 Supplier Number: 74829240 (USE FORMAT 7 FOR FULLTEXT)
PERISHABLE SYSTEMS TAKE CENTER STAGE.(Supermarket merchandising)(Brief Article)
Shulman, Richard
Supermarket Business, v56, n4, p47
April 15, 2001
Language: English Record Type: Fulltext
Article Type: Brief Article
Document Type: Magazine/Journal; Trade
Word Count: 1919

... products is changing and that the methods of procurement must change as well. In the **meat** industry we are on an inexorable path to case-ready. This change is being forced...

...The day is not far away when retailers will not be able to crew their **meat** departments with skilled employees. Unfortunately, it seems as if a week doesn't go by without reading about some recall or **food** safety problem. The problems of assuring **food** safety at store level can be addressed only partially with an aggressive **HACCP** program. Realistically, perishable production at a retail store is a time bomb waiting to explode ...

...will overlap the standard numbers assigned for another department; for example, you may be identifying **produce** items with numbers that are included in the standard UPC codes for **meat** .
All your perishable UPC coding must be reviewed for these overlaps and a corporate plan...

...you will need the pricing tools to project how much it would cost you to **produce** the same retail cuts at your stores from primals. **Simulation** tools like this will become a requirement. The Value Based **Meat** Management System is such a tool, and it could be used for other products that are prepared at store level.
Case-Ready Shrink
The downside to case-ready **meat** is that it has a higher cost per pound and a shorter case life. To...to see many perishable companies offering systems to track the temperature of product throughout the **supply chain** to ensure quality. This can result in longer shelf life and preserve the accountability of every element of the **supply chain** . Some of these devices are very sophisticated and take snapshots of conditions, logging temperature and...
...or leaving the DC. This means both lower product cost and less risk of product **contamination** or spoilage.
Controlling inventory is only part of an invigorated perishables program. You will need...
INDUSTRY NAMES: BUSN (Any type of business); **FOOD** (**Food** , Beverages and Nutrition); RETL (Retailing)
20010415

17/K/8 (Item 3 from file: 16)

09189629 Supplier Number: 63994085 (USE FORMAT 7 FOR FULLTEXT)
THE MICROFOODERY' PARADIGM.
HAMMEL, FRANK
Supermarket Business, v52, n6, p102
June, 1997
Language: English Record Type: Fulltext
Document Type: Magazine/Journal; Trade
Word Count: 1891

... could help independent supermarkets with a flair for freshness and local-market distinction offer prepared **food** menus that stand out.

But while retail alliances could **produce** whole menus of interesting products that rotate weekly and change with the seasons, retailers wouldn't have to fear their **food** prep costs would rise to an equally high profile.

And by meeting the consumer's...

...and variety, and the retailer's need for word of mouth loyalty, all within a **food** production system that offers scale economies over restaurant meal production, 'Microfoodery'-retail partnerships could flourish.

While not yielding the same economies of a **food** plant serving a nation, these regional kitchens will strive for the economies that support retail...

...to restaurant takeout as foodservice competition intensifies.

Over time, that could nudge the U.S. **supply chain** closer to the fast-and-cold deliveries that are now standard operating procedure in places...

...and other ultra-fresh products on a daily basis--Hale expects the ideal distribution/replenishment **model** to start with a regional kitchen close to clusters of stores, so that all can be reached in a driver's eight-hour shift.

As always, however, fresh **food** distribution needs critical mass to push through logistical roadblocks to long-term success, not the...

...opted to formulate their offerings so they can withstand a longer trek through the chilled **supply chain** .

"I designed a product that would work with today's distribution logistics," says Dennis Schwakopf, director of strategic project development at Mallard's **Food** Products (Modesto, Calif.).

While the first packaged fresh foods Mallard's developed had a "much ...

...days is probably the minimum" shelf life requirement for national distribution through the current supermarket **supply chain** , Schwakopf says. Even that would be too close for some. With six full weeks, they like **botulism** .

At the New England Dairy-Deli-Bakery Show in Boston in April, Ed DeLuca, president...

...concern, says Marcia Schurer, president of Culinary Connections (Boulder, Colo.), is that while manufacturers of **food** processing or vacuum-packaging equipment make a point of ensuring that their potentially hazardous machines...

...You can't make what's bad good," says DeLuca. And when it comes to **food** safety, it pays to take heed when those in charge of safety make a judgment...

...dies, you'll go to jail."

If that weren't reason enough for the retail **food** industry to work out a way to share both the costs and benefits of temperature...
...in product availability and quality.

While the growth of microfooderies, regional and multi-regional

fresh **food** plants expands the range of options, fresh prep partners still have to be screened carefully. One red flag, DeLuca says, is if the acronym **HACCP** draws a blank stare.

Another sign of trouble--when potential partners show signs of tolerating mediocrity. "You have to make sure they want to have the highest quality **food** and the highest safety standards," Schurer says, and not just when you're visiting the...

...passion, the know-how and the financial resources can follow the path blazed by fresh **food** pioneers before most of today's microfooderies existed.

At FMI's Speaks '97 presentation in...

...Super Markets (Richmond, Va.), told how that company decided to basically build its own fresh **food** **supply** **chain** from scratch.

It all started, Ukrop said, from a fact-finding mission in Europe in ...

...all about lifestyles, changing lifestyles and what the store should be selling, which is great **food** . You can design great **food** stores, but the secret is great **food** ."

Probe that secret further and you start finding some patterns for success among companies that...

...a dramatic improvement in taste, texture and shelf life and an equally dramatic reduction in **food** safety risks--adding up to a halo effect that can lift sales results store-wide...

...you make a token effort and it shows up in the form of bad-tasting **food** or, worse, signs of **contamination** , it will undermine your entire operation."

INDUSTRY NAMES: BUSN (Any type of business); **FOOD** (**Food** , Beverages and Nutrition); RETL (Retailing)

19970601

17/K/9 (Item 4 from file: 16)

DIALOG(R)File 16:Gale Group PROMT(R)

08742092 Supplier Number: 75755742 (USE FORMAT 7 FOR FULLTEXT)

President and CEO of Royal Ahold, Cees van der Hoeven, Gives Speech to the CIES World Food **Business Forum.**

Business Wire, p2202
June 22, 2001
Language: English Record Type: Fulltext
Document Type: Newswire; Trade
Word Count: 2957

...and CEO of Royal Ahold, Cees van der Hoeven, Gives Speech to the CIES World Food **Business Forum.**

PRAGUE, Czech Republic--(BUSINESS WIRE)--June 22, 2001

Social Accountability: Maintaining Confidence
in **Food** in the 21st Century
Address by Cees van der Hoeven
President & CEO
Royal Ahold
to the CIES World **Food** Business Forum 2001
Prague, the Czech Republic
Friday, June 22, 2001

Chairman,

Ladies and gentlemen, **food** is safer than ever. But that doesn't mean people believe it. I am talking to you today representing 38 international **food** retailers currently affiliated to the Global **Food** Safety Initiative Task Force. I would like to update you on what we are doing to reduce the sense of unease many consumers feel about their **food** . We cannot accept that **food** items, rightly or wrongly, are perceived by the consumer as unsafe. We will not sit...

...back to that later.

Global retailers and suppliers are taking a leadership role in maximizing **food** safety throughout the **supply chain** . We are working together on a non-competitive basis to address this truly top priority. In close cooperation, CIES and FMI have teamed up with the **food** safety specialists of leading global retailers and manufacturers to orchestrate the activities of the Task...

...their commitment to this vital initiative. We're all in this together. We cannot leave **food** safety only in the hands of governments, even though they historically ensured through legislation and controls that **food** was produced in a safe way. Governments have to change policy, focusing on the weakest links in **food** chains and recognizing the safety measures being taken by responsible **food** production and distribution players.

We as **food** retailers need to know how the **food** is made, where it comes from, how it was grown, what ingredients were added, who...

...of other major and minor issues to ensure that our customers continue to trust their **food** on safety. Over the next 15 minutes, I would like to detail some of the issues and tell you what the global **food** safety task force has done since May last year. The 38 retailers listed on this...

...that and where we stand today is what you are going to hear.

1. Global **Food** Safety Standards.

It is hard to believe that worldwide over 135 different supplier standards for **food** safety are in use today, resulting in different criteria and auditing practices and leading to negative cost implications and barriers to trade.

The Global **Food** Safety Initiative, launched in Dublin in April 2000, can only guarantee that **food** items are safe if we use fewer though stricter standards. To do so, we have...

...most from this is the consumer, whom we now provide with a global norm in **food** safety. The Task Force invested considerable time in reviewing international legislative requirements, including the Codex...
...the Task Force this month completed the set of criteria that creates a global benchmark **model** for **food** safety standards.

The **model** covers quality management systems, good practices in agriculture, manufacturing and distribution and a Hazard Analysis and Critical Control Points (**HACCP**).

To get this far in a relative short period of time, an excellent working relationship on **food** safety among global **food** retailers and manufacturers has been established. This partnership also includes participation of both large and small manufacturers and producers from the agricultural sector. Top **food** safety experts of well reputed manufacturers such as Nestle, Danone, Sara Lee, Unilever, Kraft, General Mills, Cargill and Coca Cola have confirmed the need for and acceptance of our benchmark **model** . It is their tool to boost **food** safety upstream the **supply chain** . Establishing criteria is not enough. An international auditing and certification system is also required for...

...accountability, because that is what consumers all over the world deserve. Following publication of the **model** at the upcoming CIES **Food** Safety Conference in Geneva this September, the formal endorsement process of existing **food** safety standards from organizations such as BRC (British Retail Consortium), SQF (Safe Quality **Food**) and Eurep Gap will get underway. Speed is essential as we cannot afford to lose any time.

Specific tools the Task Force of the Global **Food** Safety Initiative intends to make available include an audit protocol, a guidance document for certification...

...framework. These will be available in the second half of the year. I call upon **food** retailers and manufacturers to demonstrate their leadership in **food** safety by implementing the global **food** safety standards the moment the system is in place this Fall. Of course, retailers can only do so if they themselves apply **HACCP** -based safety procedures.

Allow me to go to ...that a restructuring of the agricultural field and production methods is imminent. A generation ago, **food** safety was not an issue that taxed the mind of more than a handful of people involved in

that specific field. **Food** was not only relatively safe, but incidences of **contamination** tended to be local in nature. Rarely did they make international or even national headlines...

...was focused on abattoirs, factories and supermarkets, and resources were invested in treating the few **contaminated** products rather than ensuring that herds or flocks were free of **contamination** in the first place.

Then as now, **contamination** of **food** took many forms, ranging from microbiological to chemical and radiological. I need hardly remind you...
...today is Chernobyl, a town that loomed into the international limelight 15 years ago when **food** **contamination** by radio-nuclides led to the **contamination** of wide areas of Europe. And more recently, the incident of toxic mustard seed in...

...for one thing, it has firmly focused the mind on the first link in the **food** chain - the farm. Put simply, if **contamination** -free animals and poultry can be ensured there, it is so much easier to keep the products free from **contamination** further along the **food** chain. That means we need to make the agricultural sector fully transparent. At the same...

...in this partnership must be the protection of the interest of the consumer. Fully controlled **supply** **chain** projects should guarantee that from "Farm to Fork" the complete production process and all its contributors take their responsibility.

The European **food** distribution sector, represented in Brussels by Eurocommerce and the European Retail Round Table, is developing...

...of government in all this, and how we strive to encourage cooperation between the worldwide **food** sector and national and pan-national governments and authorities.

3. Encouraging worldwide government cooperation.

Most quality retailers and manufacturers put the customer first and foremost. Members of the Global **Food** Safety Initiative believe that worldwide trade issues or political disputes should not be allowed to come between our core focus: the production and distribution of wholesome, nutritious **food** and related products in the safest possible way.

Trade disputes between North America and Europe...

...the world should not be an excuse to exclude a region or country from the **food** safety initiative.

As one of its other priorities, the Global **Food** Safety Task Force encourages, advances and develops cooperation between the **food** industry and government policymakers. This is all the more vital as we believe that consumer trust in the activities of government regulators to ensure **food** safety has gone down drastically, especially in Europe.

One of the main challenges for government, especially in Europe, is the need to reform agricultural policy. To maximize **food** safety, the European Commission and national governments have to eliminate structural overcapacity in the agricultural...

...information.

This can only be successful if done together with the private sector in a **supply** **chain** focused approach. The process hereto always starts with the consumer top of mind. Their wish...

...for sustainable rural development, environmental protection and animal welfare alongside the number one imperative of **food** safety. The necessary initiatives must result in a new, strong, competitive agricultural sector.

We urge...

...North America, we see a different situation. We respect for example the role of the **Food** & Drug Administration (FDA) to secure **food** safety. In our opinion, there is nothing wrong in Europe copying all the good things ...

...is also a fact of life.

4. Rapid alert system.

In this respect, the Global **Food** Safety Task Force recognizes that developing an early warning system among retailers is one other...

...is running a pilot project to test its effectiveness. Participants in the pilot are exchanging **food** safety information through the internet and keep each other ...leap forward. We have to, the consumer expects it from us.

Traditionally - and too often - **food** reaches the consumer before sufficient information is available to take a **food** safety decision. This serves neither our sense of social responsibility nor our business interests. We...

...rapid alert system would improve the speed and effectiveness of the industry's response to **food** safety crises. Such system facilitates the flow of information to all parties concerned, quickly, accurately...

...incidents impact a wider audience.

We are not limiting ourselves to communicating information expeditiously among **food** retailers. We also want to improve rapid alerts with suppliers and governments. We are working...

...on to my last theme - promoting consumer education.

5. Promoting consumer education.

With respect to **food** safety, we know the consumer's kitchen is still a weak link in the **food** chain. U.S. **food** retailers have joined forces with the FMI to develop a so-called "Fight Bac" campaign to heighten awareness of kitchen hygiene, proper **food** preparation and simple safe-**food** -handling messages directly to the consumer. And this is necessary, because research shows that consumer know-how of prevention principles to minimize **food** -borne disease is decreasing at the same rate that ready-to-(h)eat, microwave and outdoor consumption of **food** are increasing.

More graphically, over 50% of customers do not really understand new **food** technologies like irradiation, biotechnology, genetic modification or integrated crop protection. In the U.S., for...

...residues on fruit and vegetables.

The Task Force, after having completed its efforts on the **food** safety standard, will start working on consumer education and information based on the FMI experiences...

...this initiative. A worldwide approach is necessary as all people have the right to safe **food** wherever they are. That's why we call it a global initiative.

Ladies and Gentlemen, as **food** retailers and suppliers, we shoulder our responsibility squarely to provide our customers with remarkable abundance, variety and value in safe, quality **food** produced in a sustainable way. We believe this approach is the best way to increase the long-term prospects for the world's **food** industries and ensure real improvements in **food** -borne disease prevention as well as in social accountability by maintaining and boosting customer confidence in **food** in the 21st century.

We have to ensure that governments also see it this way and act accordingly. We have established the best **food** safety standards for use by all parties. We now have quality management systems in place...

...analysis and critical control points are also essential tools.

Implementation of all elements of the **Food** Safety Initiative has started and seldom have we seen such cooperation among partners that normally...

...to make consumers more aware of what they can do to help themselves.

In summary: **food** safety is on top of everybody's priority list. We have jointly developed a mission...

...position in internet-based home delivery. Ahold employs almost 420,000 associates and serves the **food** needs of over 35 million customers and more than 200,000 foodservice accounts in 25...

20010622

17/K/10 (Item 5 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

08328928 Supplier Number: 70378872 (USE FORMAT 7 FOR FULLTEXT)
Raising the standard.
White, Doug
Adhesive Technology, v17, n5, p24
Dec, 2000
Language: English Record Type: Fulltext
Document Type: Magazine/Journal; Trade
Word Count: 2151

(USE FORMAT 7 FOR FULLTEXT)
TEXT:
The British Retail Consortium, having successfully implemented hygiene standards in the **food** industry, has now completed a draft standard and certification scheme for **food** packaging manufacturers, including the adhesives sector, This article traces the development of the scheme and...
... in the way in which the majority of the UK's major retailers manage their **supply chain** with respect to product safety, legality and quality. These changes culminated in the adoption of a third party certification system for **food** manufacturers and processors. The scheme involves third party companies auditing the supplier's operations against a standard developed by the British Retail Consortium. To ensure that the **supply chain** is effectively monitored and controlled and that it meets the retailer's `due diligence' requirements...

...to be accredited by the United Kingdom Accreditation Service (UKAS). CMi undertakes audits worldwide of **food** companies supplying the major **food** retailers. The scheme is gaining increasing recognition by retailers outside the UK, especially within Europe...

...British Retail Consortium completed the development of a draft hygiene standard and certification scheme for **food** packaging manufacturers which will mirror the **model** successfully implemented across the **food** manufacturing sector. Representatives of the adhesives and coatings sector have been involved in the development...

...very beginning in the development and implementation of the Royal Society of Health's (RSH) **Food** Packaging Hygiene certification Scheme 1 continue to be amazed at the continuing high level of...

...those found anywhere in the world. Based upon my own experience of undertaking audits of **food** manufacturing sites worldwide it is somewhat ironic (and very frustrating for my clients) that certified **food** packaging companies occasionally have higher standards of hygiene than those that are achieved by their...

...I spent some time on the development of CMi's third party certification scheme for **food** manufacturers. Such schemes were being offered by a number of consultancy companies and eventually the...

...s involvement in the development and implementation of the British Retail Consortium (BRC) standard for **food** manufacturers it was recognised that a similar approach could be used for the **food** packaging industry.
CMi therefore decided to bring together the major retailers to enable them to consider the development of a unified technical standard that would follow the **model** implemented in the **food** manufacturing sector. The response was a positive one and a decision was made to develop protocols. The group comprised representatives from the **food** retailing sector, **food** packaging industry, companies involved in consultancy and audit, the major certification bodies, the Institute of Packaging, major **food** manufacturers, merchandisers and representatives of trade organisations including the adhesives and sealant sectors.
A CONSENSUS...

...encompassing hygiene standards which they had been unable to achieve in many of their existing **food** packaging suppliers. I feared that certified

companies that had well developed hygiene systems would require...

...and compliance with legal requirements relating to materials and articles which come into contact with **food** .

The new standard will therefore encompass critical aspects of the manufacturing process. Again it was...

...hazards associated with the manufacturing operation. It was recognised that Hazard Analysis Critical Control Point (**HACCP**) techniques would meet this requirement but that the standard would need to reflect the fact that the hazards within the packaging industry are significantly different from those found within the **food** industry. The vast majority of hazards are best controlled generically with the benefit that process specific hazards are normally chemical or physical. Microbiological hazards are rarely significant apart from **contamination** hazards which are best controlled generically by by implementing effective personal hygiene and cleaning procedures...

...s `due diligence' requirements.

11. Recognition of certified suppliers by BRC, Trade Organisations and major **food** manufacturers.

12. Increasing recognition by other customers e.g. **food** service sector.

13. Gradual adoption of the scheme internationally.

From CMi's experience of the **food** manufacturing scheme it is clear that there are a number of issues which **food** adhesive and sealant manufacturers need to consider even at this early stage.

SO WHAT HAPPENS NOW ...? CMI'S EIGHT-POINT PLAN FOR ADHESIVE MANUFACTURERS SUPPLYING THE **FOOD** INDUSTRY

Third party certification is likely to become a pre-requisite for supplying packaging to most of the major retailers,

Food manufacturers will `buy into' the scheme in increasing numbers.

The BRC standard is only in...

...essential that you only use companies which meet this requirement.

CMI PROVIDES CERTIFICATION SERVICES TO **FOOD** MANUFACTURERS AND **FOOD** PACKAGING MANUFACTURERS. THE CONSULTANCY DIVISION PROVIDES CONSULTANCY SUPPORT TO CLIENTS WISHING TO MEET CERTIFICATION STANDARDS...

PRODUCT NAMES: 2000000 (**Food** & Kindred Products); 2891000 (Adhesives & Sealants)

SIC CODES: 2000 (**FOOD** AND KINDRED PRODUCTS); 2891 (Adhesives and sealants)

NAICS CODES: 311 (**Food** Manufacturing); 32552 (Adhesive Manufacturing)

20001201

17/K/11 (Item 6 from file: 16)

DIALOG(R)File 16:Gale Group PROMT(R)

07180376 Supplier Number: 60091906 (USE FORMAT 7 FOR FULLTEXT)

Suppliers keep expanding services.(water treatment)(Statistical Data Included)

Reilly, Christopher

Purchasing, v128, n3, p40C15

March 9, 2000

Language: English Record Type: Fulltext

Article Type: Statistical Data Included

Document Type: Magazine/Journal; Trade

Word Count: 2622

... increasing competition and the need to improve profit margins by taking costs out of the **supply chain** , buyers of water treatment chemicals and services are moving away from some of the more...look beyond a limited-scope need, and look at how an entire facility can better **model** the way they use and manage their environmental issues, in terms of water treatment," Sabal...

...U.S. Environmental Protection Agency (EPA) to institute its cluster rules, which monitor waste effluent **contaminants** . A phase-out of chlorine use by paper mills will officially go into effect in...
...according to General Chemical's Karla Doremus-Tranfield. "There is an issue currently in the **meat** and poultry industry that concerns regulations for hazard analysis critical control points (**HACCP**), that addresses steps companies can take to reduce biological hazard levels," she says.
She explains that many companies in the **meat** and poultry market are using a procedure for washing **meat** and poultry products with trisodium phosphate. "This keeps biological hazards low, but also results in...
20000309

17/K/12 (Item 7 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

06238990 Supplier Number: 54323422 (USE FORMAT 7 FOR FULLTEXT)
Comeback in a bottle.(Odwalla makes a comeback from recall disaster)(Brief Article)
Postlewaite, Kimbra
Beverage Industry, v90, n3, p20(1)
March, 1999
Language: English Record Type: Fulltext
Article Type: Brief Article
Document Type: Magazine/Journal; Trade
Word Count: 1704

(USE FORMAT 7 FOR FULLTEXT)
TEXT:
...beverage business is only the half of it. Williamson's motto that "this juice is **food** " propelled the company into the functional **food** market beginning with the 1992 launch of Super Protein. However, Odwalla had been redefining nutritional...
... be as successful as it was, but we believed in the concept of simple green **food** ," says Williamson. "I actually shy away from that whole idea of the term nutraceuticals. I think it's about simple good **food** ."
Unfortunately, nutraceuticals was not the only area in which Odwalla was forced to lead by...

...a few pages on staging a come-from-behind victory, Odwalla's playbook also advocates **HACCP** throughout the **supply chain** , and giving back to the land that provides the fruit for Odwalla's labor.
Two...comeback, Odwalla developed a partnership with McAfee, not only as a supplier, but as a **model** for sustainable farming practices and field-based **HACCP** procedures.
"We valued the Fuji as a critical ingredient to our flavor profile. In a...

...Mark McAfee, an excellent grower, who developed a very innovative system that he calls Field **HACCP** . It's basically brilliant common sense that puts together some standards in the field, and considering all the issues around **food** safety these days, is a **model** for any tree fruit picking."
McAfee's Field **HACCP** program eliminates the opportunity for cross **contamination** in the field. For example, an employee in his orchard will not pick a piece...
...healthier, cleaner standard in the field with the pickers. There's no opportunity for cross **contamination** ; he broke those connections," says Mangan. "That's a really good relationship where he, as...

...more than $1 million in product to programs such as Second Harvest and Project Angel **Food** . In addition to supporting sustainable farming practices, Odwalla also uses old bottles to make recycled...
INDUSTRY NAMES: BUSN (Any type of business); **FOOD** (**Food** , Beverages and Nutrition)
19990301

17/K/13 (Item 8 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

05077188 Supplier Number: 47453222 (USE FORMAT 7 FOR FULLTEXT)
NRA, industry embrace HACCP system in attempt to curb food -borne illnesses
Rubinstein, Ed
Nation's Restaurant News, p70
June 9, 1997
Language: English Record Type: Fulltext
Document Type: Magazine/Journal; Tabloid; Trade
Word Count: 686

NRA, industry embrace HACCP system in attempt to curb food -borne illnesses

CHICAGO - **Food** -borne illnesses have been a bane to the foodservice industry. However, rather than reactively recant...

...Restaurant Association and the industry are proactively embracing the Hazard Analysis Critical Control Point, or **HACCP** , **food** safety system.

HACCP allows for a systematic method of analyzing a **food** process and determining the possible hazards within that process, and it applies to all stages of **food** production, from slaughterhouse to consumer consumption. Once potential biological, chemical and physical **food** hazards are identified, critical control points, or CCPs, a series of steps or procedures that...

...or hazards, are established.

'There cannot be quality without safety,' proclaimed Gary Sherlaw, vice president, **food** safety systems, for Ann Arbor, Mich.-based NSF International, a consulting firm that assists foodservice operators to become **HACCP** compliant.

Sherlaw joined Peter Slade, Ph.D., of McDonald's Corp., Donald Kautter Jr. of the **Food** & Drug Administration, John Marcy, Ph.D., of the University of Arkansas and moderator Steve Grover of the NRA in a discussion about the benefits associated with **HACCP** during the 78th annual NRA show.

Grover outlined the seven principles of **HACCP** : assessing hazards; identifying critical control points; developing criteria for CCPs, such as cooking temperatures; monitoring...

...indicates that there has been a deviation from an established CCP; documenting records of the **HACCP** system; and verifying that the **HACCP** system is working.

According to Grover's experience, record keeping has been the most difficult...

...to date for operators to incorporate.

In his presentation the FDA's Kautter noted that **food** -borne diseases are responsible for as much as $9 billion a year in lost work...

...growing number of either known or unidentifiable pathogens, the most common of which are salmonella, **botulism** and E. coli, and the country's escalating population base, which has increased the number of consumers who are susceptible to **food** -borne diseases.

A major unknown variable will be the government's role in regard to **HACCP** and the level of regulations or inspections that will exist.

While the government is involved with **HACCP** initiatives, the United States Department of Agriculture is overhauling its **meat** inspection system and the FDA recently released its **Model Food** Code, Kautter encouraged NRA attendees to adopt **HACCP** . 'Don't wait for the government to mandate it,' he said. However, Marcy noted that mandates apparently would begin at the processing plants. For example, he said, all large-output **meat** and poultry plants by January 1998 will be required to have **HACCP** programs in place.

'We are not sure how this will play out. In the past all systems were preapproved by the USDA,' Marcy said. Marcy, who has a doctorate in **food**

science, candidly noted that it would be unclear whether such mandated regulation will result in pathogen reductions.

Food that moves up the **supply chain** could place restaurant operators at greater risk for pathogens, which makes **HACCP** programs all the more critical. That realization has prompted forward-thinking chains, such as McDonald's, Marriott Management Services and Taco Bell, to establish systemwide **HACCP** programs.

' **HACCP** has been very good for us,' commented Peter Slade, manager of McDonald's **food** safety program at headquarters in Oak Brook, Ill. The sophisticated system, first developed several years...

...English and Spanish.

In his presentation Slade outlined the organizational challenges inherent in developing a **HACCP** program and provided some tips in choosing **food** safety consultants. He emphasized that organizations should utilize the proverbial acronym 'KISS,' or 'keep it simple, stupid' approach to **HACCP** . For example, he said that developing too many CCPs would make any **HACCP** program unmanageable.

As for the hiring of **HACCP** consultants, Slade was steadfast in saying that they must have knowledge of the foodservice **supply chain** as well as specific experience in their restaurant segment, whether it be quick-service, fine...

NAICS CODES: 81391 (Business Associations); 722 (**Food** Services and Drinking Places)

19970609

17/K/14 (Item 9 from file: 16)

DIALOG(R)File 16:Gale Group PROMT(R)

04022749 Supplier Number: 45847037 (USE FORMAT 7 FOR FULLTEXT)

WISCONSIN E. COLI PREVALENCE DATA FINDS WATER LINK: LUCHANSKY

Food Chemical News, v37, n33, pN/A
Oct 9, 1995
Language: English Record Type: Fulltext
Document Type: Newsletter; Trade
Word Count: 1185

(USE FORMAT 7 FOR FULLTEXT)

TEXT:

...hype" about E. coli O157:H7, Dr. John Luchansky, associate professor of microbiology, toxicology and **food** science at the University of Wisconsin, Madison, announced at the annual meeting of the American **Meat** Institute Sept. 21 24 in Chicago (See **FOOD** CHEMICAL NEWS, Oct. 2, Page 26, and following stories).

... study he recently completed involving Wisconsin dairy cattle, which also looked for environmental sources of **contamination** . A team of university, state and federal agricultural researchers conducted the Wisconsin Farm Survey and...

...Survey was unique from other studies in that it also explored possible environmental sources of **contamination** and attempted to link positive isolates by genetic fingerprinting, Luchansky said.

The researchers gathered environmental...

...of E. coli O157:H7 in hamburger at various stages of the food production and **distribution chain** .

According to Tanya Roberts, Ph.D., senior economist with USDA's Economic Research Service, a...

...was published by the National Research Council in 1983, called the Red Book four-step **model** . The **model** can be most useful "once **food** is on the fork," Roberts said, but is not particularly helpful in interpreting the significance...other risk assessment methodologies are compared."

"We believe that PSA and FTA are complementary to **HACCP** ," Roberts said, adding, "The progress in one will necessarily lead to the advance of knowledge...

INDUSTRY NAMES: BUSN (Any type of business); CHEM (Chemicals, Plastics

and Rubber); **FOOD** (**Food** , Beverages and Nutrition)
19951009

17/K/15 (Item 1 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

15770017 SUPPLIER NUMBER: 96893265 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Knowledge management and comparative international strategies on vertical information flow in the global food **system.**
Bailey, DeeVon; Jones, Eluned; Dickinson, David L.
American Journal of Agricultural Economics, 84, 5, 1337(8)
Dec, 2002
ISSN: 0002-9092 LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 5020 LINE COUNT: 00415

Knowledge management and comparative international strategies on vertical information flow in the global food **system.**

TEXT:
...Encephalopathy or BSE) in Europe and Japan, widely publicized outbreaks of E. coli O157:H7 **contamination** of ground beef products and other microbiological **contamination** scares in the **food** industry, and the recent StarLink crisis have led to rising public concern worldwide for **food** safety. The events on 11 September 2001 added a dimension of biosecurity, or intentional **contamination** in comparison with "accidental" **contamination** (Jones, 2002b). The impact of these scares on consumers, and the reaction of government and private industry to these crises, have significant implication for how **food** ingredients are assembled,

The governance institutions for agri- **food** markets in western, democratic economies have evolved over the past hundred years to take into result is a significant market population that is focused on **food** as a source of nutrition, health, and lifestyle. However, there is a continued expectation that the **food** they consume is safe.

In Schlosser's Fast **Food** Nation the lack of transparency in the **food** system was brought to the attention of the consumer in a dramatic and sensational (nonfiction...

...a fictional setting Cook elaborated on the sensational potential of resistant E. coli O157:H7 **contamination** of the ubiquitous fast **food** hamburger by using this as the focus of his mystery, Toxin. Further, by adding a...where fantasy fiction may have none.

The first significant challenge to the ability of the **food** system to meet industry and consumer demands evolved from the crossover from animal to humans...passport" (1) system, incorporating the concepts of traceability, transparency, and assurances (TTA) into the red **meat** system, was introduced to meet the new demands for accountability and responsiveness (recall) (Baines and...Uruguay are following the lead of the EU in incorporating TTA into their own red **meat** systems. However, the United States has not generally been incorporating TTA into its red **meat** marketing system. The result is a contrast between the U.S. red **meat** system and its trading partners and competitors in terms of TTA (Liddell and Bailey, Bailey...

...Lewis).

The StarLink crisis is another example of the havoc that can be caused when **food** inputs and products are co-mingled without regard to their origin. (2) StarLink gave a "wakeup" call about how difficult it would be to track and extract **contaminated** grain from the U.S. **supply chain** (Jones, 2002a). Strong economic incentives have existed for sometime in Europe for agricultural producers ...moving toward similar systems. For example, General Foods claims that by 2005 all of their **food** ingredients will be sourced via **supply chain** alliances and partnerships in order to control their risk exposure and to realize the profit opportunities from value-enhanced products (Jones, 2002a).

Recent research suggests that the U.S. **food** system is lagging other countries in the development of TTA in terms of providing traceability, transparency, and extrinsic quality assurances (Liddell and

Bailey; Jones, 2002a). The fact that **food** systems in ...3)

Definitions

Traceability is defined as the ability to track the inputs used to make **food** products upstream to their source at different levels of the marketing chain. Liddell and Bailey...

...complete" traceability would require not only being able to trace back the principal inputs in **food** products to their source at different levels of the marketing chain, but also the secondary inputs such as feed stuffs and genetic lines in the case of red **meat** .

Transparency refers to the public disclosure of information on all of the rules, procedures, and practices used to **produce** a **food** product at each level of the marketing chain (Baines and Davies, 1997; Early). Transparency provides consumers with detailed information about the processes used to **produce** a **food** product. This eliminates the "black box" of production practices and informs consumers about how the...

...produced and even elicits input from consumers about the procedures they would like used to **produce** the product.

Quality assurance has three key elements including (a) managing hygiene to ensure **food** safety, (b) ensuring quality through grading and other ...for product recalls (Early, Baines). The processes for ensuring hygiene in the EU for red **meat** have focused on Hazard Analysis Critical Control Point (**HACCP**) protocols at each point in the pork value chain. ISO-9000 and other ISO protocols are also being used for a wide range of **food** products not only to certify hygiene, but to also certify social and environmental responsibility (e.g., ISO-14000).

Ensuring quality includes measurements of the intrinsic quality of a commodity or **food** product (taste, grading, etc.). Intrinsic quality measurements of physical traits are common to most ...health, processing efficiency) or negative (possibly genetically engineered in some markets) credence value in the **supply chain** is limited by the technological ability to measure the traits and/or the economics of...

...response to consumer demand, the EU system also provides measures of the extrinsic qualities of **food** products, especially red **meat** . Extrinsic qualities do not affect either **food** safety or the intrinsic qualities of the **food** product but ...animal welfare, environmental preservation, social responsibility, or assurances about the absence of inputs used to **produce** the **food** product such as the absence of genetically modified organisms (GMOs) (Liddell and Bailey, Baines). Extrinsic...

...and other certification and labeling standards (e.g., ISO) to provide a basis for differentiating **food** products, both in international trade and domestic markets (Baines and Davies, 2000). For example, in...for "free range" eggs than for fresh barn eggs.

Potential Impact on the U.S. **Food** Chain

There are at least four reasons why the U.S. **food** industry should be concerned that it is lagging its competitors in terms of TTA. First, consumers are becoming more concerned about the inputs used to **produce** **food** . In the past, consumers viewed their primary **food** safety risk as being **food** -borne pathogen **contamination** at the processing and preparation levels. As a result, current U.S. **food** inspection, **food** safety laws, and enforcement are principally aimed at **food** processors and **food** preparers. **Food** -borne pathogens remain an important concern but emerging consumer interest centers on the inputs used to **produce** **food** such as concerns about GMOs, the effect of consumption on environmental degradation, and animal welfare...

...The current U.S. inspection system was not designed to track farm-level inputs in **food** production and significant changes, and associated costs, would be required to modify the U.S. system to do so.

Second, competitors may be able to successfully differentiate their **food** products based on TTA (Baines and Davies, 2000). This could conceivably relegate U.S. **food** products to second- ...source-verify corn during the StarLink crisis and provide documentation that the grain was not **contaminated** with StarLink corn (e.g., Consolidated Grain and Barge who are implementing ISO protocols across...

...pay for TTA and a potential market opportunity may be lost if the U.S. **food** industry fails to develop credible TTA systems. Fourth, the security of the **food** system may require a method for tracking **food** and **food** inputs rapidly to their source. A major U.S. **food** processor has suggested a target of ten minutes for tracing the point of **contamination** and issuing recall information. The current system comingles products from many producers in many locations making them almost impossible to track. The intentional **contamination** of **food** ingredient supply chains is an issue of great concern to U.S. processors and manufacturers...documentation. Further efforts would be required to protect the supply chains against efforts at intentional **contamination** . However, without the TTA framework the ability to recall **contaminated** **food** ing redients upstream from the processor is minimal regardless of the timeframe.

Sources of Friction between **Food** Systems

Several important differences exist between the U.S. and EU **food** systems that have contributed to function between the systems concerning TTA. A few of these differences are highlighted in this section.

Food Policy Relating to Risk Assessment and Risk Analysis

The development of TTA systems and the rise of the "precautionary principle" (PP) in public **food** policy in the EU signals a system experiencing a severe breakdown in communication along the...

...United Kingdom and the emerging BSE crisis, the PP began to be applied to address **food** policy concerns in the EU (Davies). The PP applied to **food** policy basically states that short-term **food** policy decisions may have long-run consequences but are often made without conclusive scientific evidence...

...have been altered to resist specific herbicides. While this does not necessarily mean that a **food** product must be proven to have no ...the sale of the product or strict labeling may be required (Davies).

The U.S. **food** industry has usually resisted these types of restrictions by the EU on the grounds that growth hormones and the more recent controversy about genetically modified (GM) foods and **food** ingredients.

Role of Public and Private Sectors in TTA

Current TTA systems in the EU...

...the public and private sectors designed to restore consumer confidence in the safety of EU **food** systems following the BSE crisis. Public assurances by European governments that there was no evidence assure the EU **food** supply badly shaken (Baines and Davies, 1997). Private companies and producer associations in some EU...

...attempted to bolster diminished consumer confidence by developing brand names that gave private certifications regarding **food** safety and quality assurance including TTA (e.g., Assured British **Meat** (ABM) and Swedish Farm-Assured (Swedish Farm Assured. Website available at http://www.healthy-tasty to provide private assurances, especially about enhanced **food** safety, which resulted in confusion at all levels of the marketing chain about what was...

...ABM was developed as a method to consolidate programs and to develop minimum standards for **food** safety, environmental preservation, animal welfare, and traceability (Fearne; Baines and Davies, 2000; Early). ABM requires EU and have adopted the private/public partnership **model** (Liddell and Bailey, Lewis). After recent confirmed cases of BSE in Japan, the Japanese government...

...they plan to move toward an EU-style animal identification and tracking system for red **meat** (Dawson).

In the past in the United States, issues relating to TTA have been driven...

...where consumers have demanded that agribusiness firms initiate TTA systems as a prerequisite to selling **food** products. For example, Wiemers once stated that traceability systems for red **meat** would not be employed in the United States unless consumers were willing to pay more...

...of the following reasons: (a) They believe TTA is being forced on the U.S. **food** system as a result of problems in the EU that do not exist here; (b) they believe that implementing such systems unnecessarily raises consumer concerns about **food** safety; or (c) they believe that imposing traceability on the U. ...typically have faced in the past (Todd). These concerns have resulted in the U.S. **food** system being slower to react to these developments than some of our major trading partners and competitors.

Industry "Captains" in the **Food** System

A key difference in the rate of adoption of TTA protocols lies not only in the lack of a life-threatening crisis relating to the U.S. **food** system, but in who drives the **food** system. In western Europe, the **food** retail companies, which evolved as the industry captains with integration back into the **food** manufacturing and processing level of the **supply chain** , have embraced TTA (e.g., Carrefour, Ahold, and Tesco). Seven of the top ten global...

...S. companies. Only WalMart, the number one global retailer, has an international presence in the **food** retail market. Conversely, in the United States the processors and manufacturers have historically maintained control over the **food supply chain** (e.g., ConAgra and Kraft/Philip Morris). However, the European retail **model** has entered the U.S. **food** system through Ahold (...eastern Europe.

With the processor and manufacturer as the industry captains of the U.S. **food** system, ensuring traceability requires building relationships in both directions along the **supply chain** -forward to retail and backward to the farm level. Given current technology in bar coding...and economic recall. Packaging materials and manufactured ingredients pose less of a threat from unintentional **contamination** , but are still at risk for biosecurity concerns.

The weakest link in the **food** supply chains occurs where the ingredients are blended, fungible commodities. Animals are individual and separable...

...the amount of information that is included with the partial carcasses and eventual cuts of **meat** . Of greatest concern is the ground beef that is formed from numerous sources of "renderings...bin contents, and is consequently not passed downstream to the commercial elevator or to the **food** or feed processor. Attempts to retain credence traits through the elevator system have been successful in the High Oil Corn **supply chain** through a series of contracts with the country elevators, and subsequently to the producers. Similarly, there are locations where higher protein wheat has been segregated to maintain value in the **supply chain** . However, while the traits have been retained, the information on management practices at each stage in the **supply chain** , and the identity of all producers and handlers associated with any "lot" of grain by...

...to recall and pinpoint with any degree of accuracy the point of unintentional or intentional **contamination** (Jones, 2002b).

Potential Costs and Benefits of Implementing TTA

While the EU has focused on implementing TTA as a foundation of its **food** marketing system, initial efforts in the U.S. **food** system have focused on exploiting niche market opportunities for TTA products. These efforts suggest that...Grannis, Hooker, and Thilmany). Dickinson and Bailey suggest that the potential market for TTA red **meat** products appears to be large. Their study uses economic experiments to determine WTP and indicates animal welfare and **food** safety (5) characteristics than they are for traceability alone. This suggests that traceability is best...the current level of record keeping at the farm-to-first-handler level of the **supply chain** , which is the weakest link in the **food** ingredient supply system. If computerized records of the activities such as variety, pesticide use, ...relationship of costs versus benefits can change dramatically if the risk associated with life-threatening **contamination** is considered. To the downstream **food** industry the cost of a product-related death will outweigh the costs of ...level the commodity producer is several steps removed from the perspective of their output as " **food** " and rarely carries product liability insurance. Unless held accountable for **contamination** in any form the producer is unlikely to consider the costs as a necessary part of doing business.

Conclusions

Food markets in developed and emerging ...protocols that require a new level of knowledge management that focuses on the processes that **produce** products rather than simple inspection of the products themselves. Process control is enabled by information...

...are willing to pay. This information also can be extended to create knowledge in the **food** system that would enable rapid trace back in times of crisis (recall or intentional **contamination**).

While TTA ...strategy in others, such as the United States.

From the perspective of marketing, whether dichotomous **food** systems can continue to exist or not depends principally on the ability of the different...

...continue to exist to provide more information on input sources and the processes used to **produce** **food** products. Designing systems that effectively gather and communicate information along the marketing chain about production...2002.

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...Chairman of USDA. FSIS Internal agency Committee on Animal Identification. Paper presented at Attacking Global **Food** and Agribusiness Barriers Conference, George Mason University, Fairfax, VA. March 1, 2001.

...DESCRIPTORS: **Food** industry

20021201

17/K/16 (Item 2 from file: 148)

15533304 SUPPLIER NUMBER: 96893266 (USE FORMAT 7 OR 9 FOR FULL TEXT)

Knowledge management in the global food system: network embeddedness and social capital.

Sporleder, Thomas L.; Moss, LeeAnn E.

American Journal of Agricultural Economics, 84, 5, 1345(8)
Dec, 2002
ISSN: 0002-9092 LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 4185 LINE COUNT: 00360

Knowledge management in the global food system: network embeddedness and social capital.

TEXT:

...are a number of events emerging that provide the incentive for analysts of the global **food supply chain** to better understand the complexity firm managers face relative to information and knowledge. These cascading events result in the need for enhanced flow of information and knowledge vertically within the **supply chain** . These events include the advent of biotechnology that has application to agricultural commodities and to **food** processing, the global concern about **food** safety, and the newest concern of animal welfare. Although these events are disparate and independent for vertical information flow in the global **food supply chain** .

... the production protocol, such as geographic origin or seed variety, at downstream portions of the **supply chain** is common (Sporleder and Goldsmith, 2001; Caswell; Hobbs and Young; Hobbs, Kerr, and Phillips). The ...

...to crop and livestock production has contributed to the need for enhanced vertical information.

Similarly, **food** safety concerns with "mad cow disease" and StarLink corn add another dimension to vertical information flow within the global **food supply chain** . The place of origin for **meat** and the assurance that flour was made from sources containing no StarLink corn are specific...

...concerns have raised specific issues about the transfer and sharing of information vertically within the **supply chain** . For example, cage space minimum requirement for chickens is now mandatory if a supplier serves certain chain restaurants (Sporleder and Goldsmith, 2002). As of March 2002 the **Food** Marketing Institute and the National Council of Chain Restaurants were establishing uniform ...Such husbandry practice information typically has not been collected or disseminated verti cally within the **supply chain** .

One recent conceptualization of the vertical flow of information problems relative to these events has...Office of Technology Assessment).

With respect to consumer behavior and foods that present a potential **food** safety hazard, evidence exists suggesting that consumers have preferences ...just perception, but a reflection of a real increase in vulnerability of household members.

General **food** safety has important implications related to antimicrobial resistance. One mechanism for exposure to resistant organisms is through direct consumption of resistant microbes from **contaminated** products. Another, and probably more important, hazard is the possibility of selection for a resistant human health is in great debate, consumer **food** safety practices play an important role in reducing any risk of exposure to antibiotic-resistant...antibiotic use take? Several possible responses exist. First, applied economists interested in the antibiotic and **food** system issue should realize that many research questions exist that do not require addressing the...the development of antibiotic resistance would appear to be economically justified. To that end, the **Food** and Drug Administration (FDA), US Department of Agriculture, and the Centers for Disease Control and...the development of cooperative responses. There are cooperative responses which are being used for enhancing **food** safety and indirectly influencing the development of antimicrobial resistance. Some cooperative responses being used by...

...of chemical and physical hazards, and system-specific on-farm Hazard Analysis Critical Control Programs (**HACCP**) (Unnevehr, Miller, and Gomez). Other cooperative responses target ...a more sophisticated understanding

of the characteristics of inter-firm vertical relationships within the global **food** system. Because knowledge is becoming recognized as a strategic asset of a firm, knowledge and logic to **food** supply chains. More typical is the analytic focus on the **food supply chain** or networks within the chain, for example, Lazzarini, Chaddad, and Cook. This focus provides only...

...capable of fostering hypotheses and analytic insights, and transcending the more mechanistic view of conventional **supply chain** analysis.

The Emergence of Knowledge Management

Especially within the last decade there is an ...both the organization and its employees, for acquiring information from internal and external sources. The **model** posits that networking improves the flow of information. The absorptive capacity of an individual or it. The **model** suggests that as absorptive capacity of an organization or an individual improves the more new knowledge is created (Powell, Koput, and Smith-Doerr). Finally, the **model** is based on the construct that knowledge creation is positively correlated with both innovation (Nonaka...move the debate further. First, a number of policy alternatives exist concerning AAU. Our simple **model** and ...models (economic or biological) of the potential externality associated with AAU deserve a rigorous critique. **Model** conclusions rest squarely upon biological assumptions that have not been proven and are the subject...19(Fall 2001):101-19.

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20021201

17/K/17 (Item 3 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

14360440 SUPPLIER NUMBER: 79076498 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Effective management of product liability risk in the United Kingdom.
Evans, John C.; Elvy, Marck C.
Defense Counsel Journal, 68, 3, 316
July, 2001
ISSN: 0895-0016 LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 4046 LINE COUNT: 00334

... directors are exposed to the risk of two categories of liability for the products they **produce** or distribute--civil and criminal. Civil liability arises from the breach of obligations or duties...

...many other specific statutory provisions regulating the manufacture and supply of particular products --for instance, **food** . The 1994 Regulations all but replaced the "general safety requirement" defined in Part II of...

...widely defined to include manufacturers, importers into the European Union, or other professionals in the **supply chain** whose activities affect the safety of the product, have a duty to ensure the safety...all reasonable steps and exercised all due diligence to avoid committing the offence."

A common **model** for a compliance system will involve the following:

* Recognition of the existence of the legal...under English law, there is an obligation on parties to an action to retain and **produce** all documents relevant and not covered by legal professional privilege. This obligation arises as soon...authorities on suppliers implementing demonstrable procedures, such as the "hazard analysis and critical control

point" (**HACCP**) principles in relation to **food** businesses, or more generally, BS 5750 and ISO 9000 systems and their successors, which embody ...

...that the supplier subsequently considers on either (1) further scrutiny, (2) reported mishap, such as **contamination** , or (3) intervention of the regulators, to be unsafe in the light of applicable product...

20010701

17/K/18 (Item 4 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

12137329 SUPPLIER NUMBER: 60582441 (USE FORMAT 7 OR 9 FOR FULL TEXT)
THE NEW ECONOMICS OF AGRICULTURE.
ANTLE, JOHN M.
American Journal of Agricultural Economics, 81, 5, 993
Dec, 1999
ISSN: 0002-9092 LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 11032 LINE COUNT: 00918

TEXT:
...mechanical technology made it possible for agricultural production to grow faster than the demand for **food** despite a rapidly growing world population. The result was a decline in real agricultural commodity...

...here as the economics of agriculture in the twentieth century. A stylized demand-and-supply **model** of an agricultural market can be used to represent these relationships, with output prices P...
... the properties of these demand and supply functions at the various levels of aggregation (the **food** demand and production literatures), the operation of agricultural markets (the industrial organization of agriculture literature...

...an array of increasingly specialized goods and services, including the diversity of manufactured foods and **food** services that substitute for time spent preparing foods from raw ingredients in the home. The...

...a product quality variable, Q, to both the demand and the supply sides of the **model** in (1):
(2) (X.sup.D) = D(P,I,N,C,Q)
(X.sup.S...

...safety attributes of foods. In addition, Q can represent many other attributes of agricultural and **food** products, notably, where and how the product was produced, including environmental attributes of the production process, and what process and inputs were used to **produce** it (e.g., pesticides, irradiation, genetically modified organisms, livestock confinement). Thus, although I will refer...

...is important to keep in mind that this variable can represent many different features of **food** products in different contexts. The key feature, as will be shown in the following, is...

...equation (2) and their implications for the effects of economic growth on the agricultural and **food** sectors of the economy. Second, I will discuss properties of markets for product quality information and their implications for the design of information-based policies for the **food** and agriculture sectors.
Markets for Quality-Differentiated Products
Following the demand literature, a decision maker...

...by the quantity of foods consumed, their quality attributes, and any other attributes of a **food** product that signal information relevant to the consumer's choices. Among these attributes may be...

...of "genetically modified" crops or animals, irradiation, and so on. For

the purpose of understanding **food** demand, it is important to distinguish the "objective" or "scientific" knowledge about the health, safety, or other characteristics of **food** products from consumers' subjective assessments of these characteristics. The two may or may not coincide...

...fundamental constraint on consumer choice is the time available to household members. A utility maximization **model** with these features can be used to derive an individual decision maker's demand functions...

...e.g., elderly consumers may be at higher risk of illness or death from certain **food** pathogens). Following the hypothesis that individual characteristics are distributed in the population of economic agents...in the form given in equation (2) can be derived (Antle, 2000).

This type of **model** shows that the demand for specialized **food** products and **food** services increases with the opportunity cost of time. Other factors driving this behavior are labor...

...and other changes in working patterns and household structure that increase the demand for specialized **food** products and services. All these factors lead to the result that the income elasticity of...

...as has been found, for example, in the analysis of quality control systems in the **food** safety literature (Unnevehr).

Given a time path for the exogenous variables (e.g., population characteristics...

...so that consumers can obtain higher-quality products for a given real price.

Agriculture, the **Food** Industry, and Economic Growth

Two facts well-established in the literature on the economics of...

...to subsidize agriculture. The first of these facts can be derived from the two-sector **model** of general equilibrium (Anderson, Johnson 1991). The key assumptions in this **model** are Engel's law (income elasticity of demand for **food** less than one) and a positive rate of per capita income growth. Another factor driving...

...short-term deviations from this pattern (Antle 1996).

A broader interpretation of the general equilibrium **model** with economic growth is that not only agriculture but more generally all sectors of the...with convenience and other attributes (Schluter, Lee, and LeBlanc). Existing studies that distinguish between raw **food** products and processed and prepared foods are based on cross-section data from high-income...

...data used to construct figure 1.

The relatively low income elasticity of demand for all **food** means that **food** declines as a share of personal consumption expenditures and as a share of GDP, but...

...elasticity of demand for convenience and other attributes means that consumption of prepared foods and **food** consumed away from home increases. For example, in the United States from 1950 to 1988, data show that **food** consumed at home declined from about 26% to 7% of consumption expenditures, whereas **food** consumed away from home increased from about 5% to about 6% of consumption expenditures (figure...

...in the twenty-first century, more of U.S. consumers' incomes will be spent on **food** consumed away from home than in the home for the first time.

With the demand and supply function properties described in the previous section, **model** (2) implies that with income growth demand shifts toward higher-quality, higher-cost (e.g...

...United States, in the aggregate, during the latter half of the twentieth century. According to **model** (2), this pattern is an outcome of the postindustrial stage of economic growth, just as...

...price patterns in figure 4 have implications for the industrial organization of agriculture and the **food** industry that we are only

beginning to understand (see, e.g., Morrison Paul and related papers). The early analysis of the **food** industry beyond the farmgate focused on marketing margins that were assumed to be fixed markups...

...George and King). The next stage in the analysis of the marketing system was to **model** the farm-to-retail price spread and to treat it as a function of marketing...

...in Gardner's (1975) influential work. However, in the postindustrial phase of economic growth, the **food** industry beyond the farmgate involves much more than the marketing of agricultural commodities. The rise of the processing and retailing segments of the **food** industries associated with modern and post-modern economic growth is the response by the **food** industry to the increasing demand for quality-differentiated **food** products with a wide array of quality attributes. Thus, agr icultural commodities increasingly become one of many inputs into a multilevel system of transportation, processing, production of **food** ingredients and ready-to-eat foods, storage, and wholesale and retail distribution.

The "industrialization of...

...of the agricultural production system. To understand the changes taking place in agriculture and the **food** industry, it is essential for economists to recognize that equally profound changes are taking place in the **food** industry that links **food** production to the consumer. The growth and increasing size and specialization of firms in the **food** industry have far-reaching implications for the way in which agricultural productivity and competitiveness operate...

...possible by this concentration (Taylor). Various studies have attempted to measure market power in the **food** sector and to assess whether the efficiencies gained through large size and concentration outweigh possible ...measure be used. Following this principle, note that the price in one stage of the **supply chain** relative to another measures the average value added at that stage plus any premium derived...

...given the high degree of concentration at the wholesale level.

The alternative hypothesis implied by **model** (2) is that the costs of demand-driven product differentiation have been equally distributed between...

...positive trend for beef), thus contradicting the argument that the rapid growth in concentration in **meat** packing increased the degree of market power in the industry. The wholesale to retail margin...

...a fact again inconsistent with a high degree of market power being exerted by the **meat** packing industry relative to the retail sector. The latter trend could be rationalized only by...

...the product differentiation hypothesis.

Interestingly, the policy debate that has arisen over concentration in the **food** industry closely parallels the debate about farm price support policies that took place in the...

...agricultural sector.

Similarly, the foregoing analysis suggests that policies attempting to prevent concentration in the **food** industry would be attempting to reverse the consequences of long-run trends in demand and...

...in the literature.

First, as discussed previously, higher-quality products are generally more costly to **produce** , so firms must charge commensurately higher prices. However, in imperfectly competitive markets or in markets...through use after purchase. For example, consumers cannot usually test foods for chemical or pathogen **contamination** , and such **contamination** might not be discerned through the experience mechanism because consumers cannot determine the source of...

...information markets from operating effectively in many cases.

Information-Based Policies for Agriculture and the **Food** Industry

The distinction between information as a public good and as a club good has...

...agents. When information is a public good, economic theory shows that private agents do not **produce** an efficient amount of product-quality information, and thus markets will not efficiently provide products...

...the market does not provide (as illustrated by the discussion of market failure in the **Food** Safety and Inspection Service's regulatory impact assessment of recent **food** safety regulations). This reasoning rationalizes the wide array of government policies and regulations related to...

...marketed directly to consumers, but the costs of preserving the identity of the ingredients of **food** products will increase with the degree ... increase.

Private and Public Good Attributes

Some product-quality attributes, such as those related to **food** safety, can be strictly private goods in the sense that they affect an individual's...in the sense that it does not provide the consumer with the choice between a **food** produced with wheat from a commercial grain farm and a **food** produced with wheat from a family grain farm.

In fact, the market does not fail...

...uses comes from an integrated operation with "family farm" and related grain-quality attributes. Many **food** products are marketed in large retail stores with packaging and other information designed to convey...that now exist in the United States to promote conservation and protection of the environment.

Food Safety

Labeling is utilized in the United States for nutrition information and is being discussed increasingly as an efficient mechanism to implement **food** safety and related **food** policies in place of less efficient command-and-control policies (Antle 1995, Caswell, Caswell and...

...and to label irradiated meats accordingly. Another example is the decision by the U.S. **Food** and Drug Administration (FDA) to allow the use of recombinant bovine somatotropin (rBST) to increase...

...an attribute can be indicated (as in rBST).

Organic foods lie at the interface between **food** safety and environment (Klonsky and Tourte). The Organic Foods Production Act of 1990 instructed the...

...with choices, the government's role should be limited to ensuring that information provided about **food** products is accurate.

Trade Policy

The Uruguay Round of the GATT negotiations brought agriculture into ...

...EC-produced beef. A policy to allow the use of hormones and to allow that **meat** certifiably produced without hormones to be so labeled would be a more efficient policy, as...

...consumers to choose between meats with these attributes. An alternative policy would be to allow **meat** produced with hormones to be sold and to require that they be so labeled. As...States and other countries. For example, the proposal by the USDA to allow irradiation of **meat** but to require labels could violate the WTO's standard because scientific risk assessment data...

...the product in its imported form (Brester and Smith). Some representatives of the U.S. **meat** industry have encouraged lawmakers to require the **meat** processing industry to maintain country-of-origin labeling for processed and retail **meat** products on the basis of the claim that consumers prefer domestically produced products. One problem...

...labeling is that it can be costly to preserve country-of-origin identity through the **supply chain** . Thus, fr om the perspective of efficient policy, the current policy of allowing but not...

...Development and Developing Countries

In conclusion, I would like to briefly discuss some implications of **model** (2) for developing countries. As I noted previously, the rapid growth of the **food** industry beyond the farmgate, as well as the declining share of agricultural commodities in the value of **food** products, is a characteristic of high-income countries. In the most remote and lowest-income areas of the world, almost all **food** consumed at home is made from unprocessed agricultural products produced locally, and the share of...

...countries is low and declining.

One result of these differences is that the price of **food** in high-income countries is influenced much less by the price of agricultural commodities than...

...same choice might result in a much larger increase in the per unit cost of **food** in a low-income country. This effect is magnified by the larger share of income spent on **food** by consumers in low-income countries compared to high-income countries.

The same logic implies...

...composition of research spending could have significant implications for the long-term trends in global **food** demand and supply balance. We know that the downward trend in real commodity prices in...

...that declining rates of public sector agricultural research investment could adversely impact the glo bal **food** demand and supply balance in the twenty-first century (Hayami and Otsuka, Ruttan 1996, Tweeten...

...productivity growth in the production of basic agricultural commodities and higher productivity growth in the **food** industry beyond the farm gate. These trends might mean that the economics of agriculture in...for applied economics research. One implication is that consumers might not accept scientific assessment of **food** safety risks or risks associated with the use of genetically modified organisms.

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19991201

17/K/19 (Item 5 from file: 148)

11564377 SUPPLIER NUMBER: 57578869 (USE FORMAT 7 OR 9 FOR FULL TEXT)
The 1999 FOOD **PROCESSING AWARDS.**
Food Processing, 60, 10, 20
Oct, 1999
ISSN: 0015-6523 LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 7075 LINE COUNT: 00604

The 1999 FOOD **PROCESSING AWARDS.**
Our salute to excellence in processing, ingredient, automation and packaging technologies.
Since 1966, **FOOD** PROCESSING has sponsored biennial awards for best new products and processes for the **food** and beverage industry. Combining imagination and ingenuity with red-hot technology, our suppliers consistently create new, higher-quality, labor- and cost-saving products and systems to benefit both **food** processors and consumers.
Our panel of industry experts has selected winners in the categories of...

...helping to reduce costs, increasing productivity, adding value to manufacturers' products, and significance to the **food** industry.

FOOD PROCESSING is pleased to announce the winners.

Award of Excellence

Guided Microwave

Spectrometry (GMS)

Epsilon...

...not just the surface or a lab sample.

By providing accurate and rapid analysis of **food** mixture components, GMS helps reduce costs in equipment, testing time, sample preparation and handling, and...

...percent improvement in standard deviation of final product over conventional lab analysis in a working **meat** processing plant.

The GMS technology allows **food** processors to offer a finished product that maintains international standards, ensuring that the **food** product produced in Australia is identical to that produced in Brazil.

GMS permits **food** processors to increase quality, throughput, productivity and profitability, while reducing costs associated with testing, calibration...

...long-term cost of ownership. It is well suited to dough, cheese, ground or emulsified **meat** , peanut butter, candy, beverages, grains and many other **food** products. The GMS provides numerous benefits across a wide spectrum of **food** applications, setting a new standard in quality control and productivity.

"Microwave Spectrometry is a revolutionary patented technology which enables **food** processors to improve throughput, quality and profitability. GMS permits processors to automatically analyze and control **food** applications previously considered impossible or cost-prohibitive using any other available in-line technology," says...

...Suite

The Foxboro Co.

The I/A series Batch Suite provides data about the entire **food** production line, integrating data collected by on-line sensors with information needed by back-office...

...batch control, real-time information, and ERP integration functionality.

Using this tightly integrated information system, **food** manufacturers can be assured maximum alignment of plant floor operations with their highest-level business...

...and scaleable software solution available for reducing costs, increasing productivity and continuously adding value to **food** product.

High Honors

Maxxum Ecolab Inc.

The Maxxum system permits on-site formulation of chemicals used to clean and sanitize **food** processing facilities. It is akin to a mini-manufacturing plant, capable of making 174 products tailored to the needs of the plant.

With Maxxum, the **food** processor can program the specific application to be cleaned and dispense the exact amount of...

...a highly resistant plastic material (PEEK) that meets the extremely exacting hygienic demands of the **food** industry. Designed without joints, it has no crevices.

An external temperature sensor that ...a single source of equipment control. Key supplies vibratory conveyers, inspection and quality monitoring systems, **food** processing and preparation equipment. This full systems approach makes "one-stop shopping" for processing a...

...Petrifilm Rapid S. aureus (RSA) Count Plates provide rapid identification of staphylococcus aureus bacteria in **food** and beverage products. They provide results equivalent to the combined three-plate Baird-Parker agar...

...test procedure. Results are available after only 26 hours of incubation.

Petrifilm RSA Plates provides **HACCP** verification of effective environmental sanitation and a **food** microbial risk assessment.

Achievement Award
High Deflection
Electromagnetic Feeder
Eriez Magnetics
Eriez's new High...

...and databases for a uniform, open and scaleable plant-wide control solution.

Achievement Award
JBA **Food**
JBA International

The JBA @ctive Modeler, a powerful yet simple-to-use graphic process mapping product inherent in JBA **Food** , can help a company redefine its operation by reducing lead and cycle times and head...

...system can prioritize work loads and notify employees of required action.

@ctive Modeler and JBA **Food** increases **food** safety levels by instantly and accurately notifying customers and suppliers of product recalls through its...
...requirements, with 3A, EHEDG, and ASME Bioprocessors Association approvals.

Achievement Award
Demand Chain Voyager and **Supply Chain** Voyager
Logility Inc.

Logility's Demand Chain Voyager and **Supply Chain** Voyager system builds collaborative relationships among businesses, distributors and customers through use of the Internet...

...world's first implementation of an Internet-based Collaborate Planning, Forecasting and Replenishment (CPFR) business **model** , the Voyager system was implemented by Heineken USA. It had a reduction in inventory from...

...Floatation (BAF), and other conventional olive processing equipment.

The Oberti olive plant was the first **food** industry processing plant to achieve zero discharge. The technology is completely automated, requiring minimal labor...of shelf life and/or the condition of the product at specific points in a **food** safety or **HACCP** program.

Vitsab tags work on a biochemical principle and have four distinct advantages: 1) they are inexpensive, 2) they have a definite starting point, 3) they are adaptable to any **food** type, and 4) they are not susceptible to false positives.

Processors will experience fewer claims...

...is inexpensive, easy to use, and is recommended by the federal government for use in **HACCP** compliance.

High Honors
SuperCONTACT Freezer
Northfield Freezing Systems

For rapid and efficient crust freezing of a wide range of products, there's no match for Northfield Freezing Systems' SuperCONTACT **Produce** Surface Freezer. **Food** products are carried on a thin, continuous film conveyor over a low-temperature plate filled...

...approved antimicrobial treatment, greatly reduces E. coli O157:H7, Listeria monocytogenes, and salmonella typhimurium in **meat** . The actual process includes three steps: water removal, steam pasteurization (over pressure) and rapid chilling...

...available microbial detection limit of 0.04 CFU/CM2 as specified in the USDA/FSIS/ **HACCP** antimicrobial program. The system reduces recalls of **contaminated meat** products.

The blanket effect of pressurized steam achieves uniform bacterial reduction over the complete carcass...
...automated system means no operator errors. It can be a critical control point in a **HACCP** plant program, with less down time.

Pasteurization dwell time, pasteurization temperature, chill water

temperature, and...to ensure consistency in appearance.
The BC-10 measures color in most bakery and snack **food** products, block yeast, brown sugar, calcium propionate, and flour blending. It quickly identifies preferences of...

...bulk sacks under vacuum. It simplifies the labor-intensive operation of loading and feeding dry **food** ingredients into a mix tank, and wets out product substantially faster with lower maintenance requirements...

...The new open throat NEMO pump with an oversized auger design handles all types of **food** products. The NM pumps convey fruit processed slurry, apple waste, grape pulp, and crushed cherries...

...of heat exchangers.
The open throat pump is ideal for conveying non-flowing components in **food** -related applications.
Achievement Award
Stonclad UT Floor System
Stonhard Inc.
Stonclad UT utilizes a multi-functional urethane-urea chemistry uniquely resistant to thermal shock and cycling conditions common to the **food** and beverage industry.
Because Stonclad UT is seamless and stands up to harsh conditions without...

...of Excellence
VersaTray
Eastman Chemical Co.
The VersaTray plastic program actually brands the package so **food** processors can capture more value for their prepared foods, making the package itself a major marketing tool. **Food** processors can sub-license the use of the brand to use VersaTray for their packaging...

...Because VersaTray plastic can be frozen, heated in a microwave or baked in an oven, **food** processors can prepare foods, flash freeze them, ship them, and have them baked or cooked...

...VersaTray label throughout the grocery store on various packages--in the home meal replacement display, **meat** case, deli and frozen case. The logo was tested with consumers to ensure that it...
...key message: dual-ovenability and flexibility.
The product has satisfied FDA and EEC high-temperature **food** contact regulations, has no effect on **food** taste or aroma, and is environmentally responsible (recycle code "...is an "intelligent" label that is a visual indicator of whether a package of refrigerated **food** has been stored for the proper time and at proper temperatures--from **food** processor to retailer to consumer. The label utilizes a temperature-sensitive material that changes from...

...of dry product. Comprising a modular steel frame on an industry-standard steel pallet and **food** -grade polypropylene panels, the container locks securely together to provide rugged, tamper-evident product protection...

...a recyclable TNT liner, the Pallecon 330 provides hygienic protection for a broad range of **food** , dairy and beverage ingredients.
The 330 can be 20 percent more efficient in shipping and...

...one of the most extensive and thorough safety testing programs ever conducted on a new **food** ingredient. More than 100 scientific studies conducted during a 20-year period clearly demonstrate the...

...everyone. In April 1998, the FDA granted approval for the use of sucralose in 15 **food** and beverage categories, including baked goods and baking mixes, beverages, dairy products, processed fruits and...

...Tate and Lyle PLC, a world leader in sweeteners and starches.
High Honors
METHOCEL A150 **Food** Grade
Dow Chemical

Dow's METHOCEL A150 **Food** Grade, a plant-based egg white replacement, is a breakthrough because it provides the highest...provide increased yields. It has exceptional cold binding and thermal gelation properties that stabilize formed **food** products at very low use levels. It provides the ease of powdered ingredient handling vs...

...seasonings to snacks because it is a dry-applied system. Before DRY-TACK adhesion system, **food** processors used oils, water or other liquids to adhere seasonings to snacks.

Because less seasoning needs to be used, since less falls off the snack, the system helps **food** processors reduce costs and waste. The need for a second snack drying operation is eliminated because no liquids are used.

DRY-TACK adhesion system helps **food** processors increase productivity, since they can ship product more quickly with no second drying operation needed.

Food processors can add value to their snacks with DRY-TACK because it holds more seasoning...

...low-fat snacks now is possible.

DRY-TACK adhesion system is significant because it helps **food** processors lower costs, increase productivity, enhance quality and solve a problem that consumers have had...

...470

A.E. Staley Manufacturing Co.

MIRA-THIK 470 is a cold water-swelling, modified **food** starch designed for neutral to mildly acid **food** systems with little shear. The instant starch maintains its granule integrity, producing finished formulated products...

...and agglomerated form, which reduces lumping and hydration problems.

Achievement Award

Soyarome Gist-brocatles/DSM **Food** Specialties

Gist-brocades' fermentation technology has produced the first true **vegetable** , dairy and spice flavor enhancer. Soyarome, a fermented soy flour, increases flavor profiles by enhancing...

...is added. SAIB has regulatory acceptance in more than 40 countries.

Achievement Award

OptaMax

Opta **Food** Ingredients Inc.

OptaMax is an amylose/lipid complex made from high amylose cornstarch

...rosemary extract, it protects against oxidation that can cause undesirable flavor and color changes in **food** and beverage products, thus extending shelf life. The product requires no dispersion. It can be...

...master's degree in chemical engineering from Cornell University and a doctorate in agricultural chemistry/ **food** science from the University of California, Davis.

George Chumakov is a product system manager for...

...and Europe. He holds a bachelor's degree in chemistry, a master's degree in **food** science and an MBA in finance.

Currently senior manager, packaging, for Lockwood-Greene Engineers, Cincinnati...

...Brend King, a partner with Process Innovations, St. Joseph, Mo., has been employed in the **food** processing industry for more than a decade. His experience includes the design and building of...

...design/layout, process improvements and project management.

Frank Kramer is president of Fremark Co., a **food** industry consulting firm based in Briarcliff Manor, N.Y.A chemical engineer, Kramer specializes in **food** process and equipment development and commercialization. He has worked in technical and managerial capacities for ...

...applications and human-machine interfaces. Next he spent two-and-one-half years with the **food** science department at Purdue University as manager of the Computer Integrated **Food** Manufacturing

Center. Currently Wert is the archive administrator and Webmaster for the Center for Education...

...INDUSTRY CODES/NAMES: **FOOD** **Food** , Beverages and Nutrition
19991001

17/K/20 (Item 6 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

10157829 SUPPLIER NUMBER: 20045359 (USE FORMAT 7 OR 9 FOR FULL TEXT)
A winning combination in Vegas. (International Exhibition for Food **Processors and Pack Expo West)**
Prepared Foods, v166, n10, p107(4)
Sep, 1997
ISSN: 0747-2536 LANGUAGE: English RECORD TYPE: Fulltext; Abstract
WORD COUNT: 1057 LINE COUNT: 00096

A winning combination in Vegas. (International Exhibition for Food **Processors and Pack Expo West)**

ABSTRACT: The International Exhibition for **Food** Processors and Pack Expo West will join efforts in presenting a diverse line of services and equipment for the **food** processing industry. The two trade shows, which will be held at Las Vegas, NV, will...

TEXT:
...one great event. If you are looking for the newest innovations and technologies in both **food** manufacturing and packaging equipment, then there's nothing better than Vegas in October.
When the International Exhibition for **Food** Processors (IEFP) and Pack Expo West join forces next month at the Sands Expo and Convention Center in Las Vegas, more than 15,000 **food** industry professionals will descend upon 400,000 sq. ft. of exhibition space, seeking the latest...

...any other key position throughout the plant.
Individually, IEFP '97, which is sponsored by the **Food** Processing Machinery and Supplies Association (FPM&SA), is one of the only true horizontal **food** processing equipment shows, attracting suppliers and buyers from a balanced mix of industries such as snack; dairy; canned; convenience; **meat** ; seafood; frozen; ethnic; fruits; vegetables; bakery goods and poultry.
Co-locating with Pack Expo West...

...20% from Africa, South America and other regions.
In response to environmental concerns of Asian **food** and beverage processors, IEFP will offer a special seminar series at the show. Topics will...

...Environmental partnership, part of the U.S. Agency for International Development. More than 400 Asian **food** and beverage processors are expected to attend the Expo this year, 33% more than the...

...Interface
Zipper-Fastening Options for Flexible Packaging
Closure Considerations in Converting from Glass to Plastic **Food** Containers
* Packaging and **Supply** **Chain** Management
Designing and Handling Primary and Secondary Packages to Meet Today's Changing Market Demands
* Processing, Filling and Handling Non-Traditionally Shaped and Sized **Food** & Beverage Containers
Versatility AND Speed. You CAN Have Both!
Adapting Production Lines to Fill, Convey, Cap, Label and Case Unusually-Shaped Glass Bottles
* Using Computer **Simulation** to Understand and Improve System Dynamics
Maximizing 'Real-World' Line Efficiencies with Virtual

Packaging/Production...
...Line
Bringing an Overseas Workforce Up to Speed
* Production Challenges of Barrier Material Options for **Food** Packaging
Changing Your Packaging Lines, QC and Mindset to Accommodate the Revolution in Case-Ready...

...Pulsed Light Technologies to Eliminate E.coli in Apple Juice and to Deactivate/Reduce Microbial **Contamination** in Aseptic Juice Packaging
An Assessment of Hot-Fill vs. Cold-Fill Aseptic Juice Processing
Improving Juice Good Manufacturing Practices and **HACCP** Procedures Through the American Fresh Juice Council (AFJC)
* Flexible Manufacturing: Agility and Production Efficiency
Flexibility...

...New Guidelines, Technical Bulletin
Common Bar Coding Crimes
* Technological Advances in Tomato and Tomato-Based **Food** Processing
Processing Techniques to Improve Quality and Shelf-Life
What's New and What's...

...to Remain a World-Class Tomato Processor in the 21st Century
Wednesday:
* Polymers and the **Food** and Beverage Packaging Lines of Tomorrow
* Beyond Heat Processing: Advances in Non-Thermal Processing Techniques...

...Moves Beyond Novelty Status
* Secondary Packaging Systems that Respond to Streamlined Distribution Patterns
* Fresh-Cut **Produce** Packaging: Beyond Polyethylene Bags Packaging Transforms Value-Added **Produce** into Modern Home Meal Replacement Options

...INDUSTRY CODES/NAMES: **FOOD** **Food** , Beverages and Nutrition
DESCRIPTORS: **Food** industry...
; International Exposition for **Food** Processors...
PRODUCT/INDUSTRY NAMES: 2000000 (**Food** & Kindred Products)
19970900

17/K/21 (Item 7 from file: 148)

09917135 SUPPLIER NUMBER: 19934620 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Food safety, software, services. (includes related article on the effect of novel processes on microbial inactivation)(IFT Food Expo Report)
Prepared Foods, v166, n9, p57(5)
August, 1997
ISSN: 0747-2536 LANGUAGE: English RECORD TYPE: Fulltext; Abstract
WORD COUNT: 1761 LINE COUNT: 00150

Food safety, software, services. (includes related article on the effect of novel processes on microbial inactivation)(IFT Food Expo Report)

ABSTRACT: Several new equipment and software for **food** industry applications that were displayed at the Institute of **Food** Technologists 1997 Expo are presented. Among the new equipment are Werner and Pfleiderer Corp's...

TEXT:
Oxygen absorbers for **food** packages are available in several styles - label types for affixing to the inside of flexible...
... development of formulations and new products, and low-volume production of cereal, gum, licorice, pet **food** and starches. Available in speeds of 600 rpm or 1200 rpm. Features include swing-arm...

...beverages with better organoleptic qualities and extended shelf life.

Research shows that most bacteria in **food** can be killed by pressures in the range of 400-800 MPa. Quintus QFP-6 lab unit can accommodate 1.4 liters of product and can **produce** pressures up to 900 MPa.

ABB Autoclave Systems.

On-line NIR sensor continuously measures fat...

...nuts. Sensor is enclosed in a stainless steel housing to meet sanitary requirements. Cables are **food** -grade glanded and the measurement is taken through a **food** -safe sapphire optical window.

Infrared Engineering.

Yeast and mold count plates have been approved by...

...Official Method. Approval is based on the results of a collaborative, comparative study of six **food** products by 18 labs. Petrifilm plates provide accurate counts in just three steps - inoculate, incubate...

...between Tragon and Audits International.

Tragon Corp.

Ozone has been declared GRAS for use in **food** manufacturing by a panel of experts from **food** science, ozone technology and other related fields. Ozone has been shown to be a more...

...components are mounted on a stainless steel skid.

Silverson Machines Inc.

Rapid microbial test allows **food** manufacturers to determine the efficacy of the their cleaning and sanitation programs, Good Manufacturing Practices and **HACCP** efforts. In addition to microorganisms, the system detects **food** residues by measuring adenosine triphosphate (ATP). Tests results are available in one minute.

IDEXX Laboratories...

...missing tabs, cocked caps and leaks.

Thermedics Detection.

Process manufacturing software understands the needs of **food** and beverage processors, tackling such concepts as intermediates, raw materials, formulas, lot strength factor, batch...through sight glasses into process vessels, such as fluidized bed or spray dryers.

Kett.

Global **supply chain** management software provides communication across the entire **supply chain** , improved management of resources and suppliers, automated order entry systems such as EDI, multi-site...

...and reduced sales order cycle time.

QAD Inc.

Colorimetric assays can detect a variety of **food** -borne pathogens - Salmonella, Listeria, L. monocytogenes, E. coil, Staphylococcus aureus, Campylobacter and Yersinia enterocolitica. Negative...

...sealed aseptic bag liner which allows the user to dispense product multiple times without air **contamination** .

Spartanburg Steel Products.

Sensory analysis software for Windows allows flexible design of questionnaires, multi-media...

...weeks.

CAMO ASA.

RELATED ARTICLE: Session 20: Effect of Novel Processes on Microbial Inactivation

To **produce** fresh-like foods and avoid, the degradation caused by heat, many **food** and beverage manufacturers are examining non-thermal processes (i.e. high-pressure) for the preservation...

...the greatest hurdles to the commercial application of these newer processes is the question of **food** safety: Can these technologies destroy pathogens and **produce** wholesome foods?

Researchers at the FDA's National Center for **Food** Safety and Technology, Summit-Argo, Ill., conducted two studies on the effects of high-pressure processing on two **food** -borne pathogens - Clostridium botulinum and Bacillus subtilus.

In one study, C. botulinum type E spores...

...to 60 (degrees) C) for three, five, eight or 10 minutes in an ABB Autoclave **Model** QFP-6 high-pressure unit.
The experiments indicated that temperatures below 35 (degrees) C with ...

...INDUSTRY CODES/NAMES: **FOOD** **Food** , Beverages and Nutrition
DESCRIPTORS: Institute of **Food** Technologists...

... **Food** processing machinery...

... **Food** industry
PRODUCT/INDUSTRY NAMES: 5084551 (**Food** Products Machines Whsle...
19970800

17/K/22 (Item 8 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB
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08694886 SUPPLIER NUMBER: 18285277 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Safety raiser: at the Speaks session, Wegmans' president urges retailers to be more responsible for food **safety. (Wegmans** Food **Markets President Daniel Wegman addresses** Food **Marketing Institute's 1996 annual convention)**
Zwiebach, Elliot
Supermarket News, v46, n20, p1(2)
May 13, 1996
ISSN: 0039-5803 LANGUAGE: English RECORD TYPE: Fulltext; Abstract
WORD COUNT: 1202 LINE COUNT: 00094

Safety raiser: at the Speaks session, Wegmans' president urges retailers to be more responsible for food **safety. (Wegmans** Food **Markets President Daniel Wegman addresses** Food **Marketing Institute's 1996 annual convention)**

ABSTRACT: The issue of **food** safety is of utmost importance in the grocery industry, according to Wegmans **Food** Markets Pres Daniel Wegman speaking at the **Food** Marketing Institute's 1996 annual convention. Wegman feels that the foods the grocery industry offers...

TEXT:
...years of side-stepping the issue, it's time for retailers to take responsibility for **food** safety, Daniel Wegman, president of Wegmans **Food** Markets, Rochester, N.Y., said here last week.
Addressing attendees at the State of the **Food** Industry: Speaks 96 presentation at the **Food** Marketing Institute's annual convention, Wegman also said his chain is considering switching to more...

...because of the costs involved in ensuring the safety of fresh products.
According to Wegman, **food** safety should not be used as a competitive tool "because that only sends a negative...

...health, all of us have a problem."
He said the industry cannot afford to take **food** safety for granted. "As an industry, we have to take responsibility for ensuring that the **food** products in the retail store are as safe and wholesome as possible.
"But for years...

...sidestepped that obligation, saying it is the job of government and suppliers to protect the **food** supply.
"Today it is time for retailers to step up and assume leadership in this area. As the last link in the **supply chain** , we can provide the final safety checks before **food** products reach consumers' hands."
Although Wegman appeared in person during the Speaks presentation, he also...

...his company's growing interest in using outside suppliers.
"We've produced a lot of **food** in stores," Wegman said in the video

segment. "However, we find that some of the measures necessary to ensure that the **food** is safe are very difficult to maintain across every item that you might **produce** .

"So we're really questioning, from a **food** safety standpoint, whether we can do the job that is required profitably Because even if...

...provide us with a number of goods.

"In fact, we have a whole wall of **food** on (one) side of the store that is produced for us by outside suppliers. And they have the volume and the expertise to **produce** very safe **food** and very good **food** , too."

Joining Wegman in the video segment was Bill Pool, Wegmans' manager of **food** safety and regulation, who echoed his boss' remarks. "As we look at the **supply chain** , we've recognized that we need to do business differently than we've done in...

...As an example, Pool noted that the chain's ground beef supplier tests for bacteria **contamination** before the product is shipped, "and it also controls the slaughter operation - it's all...

...there's a potential for a problem."

To raise the level of employee expertise in **food** safety, Pool said Wegmans introduced a more formalized approach to training last summer, consisting of...

...microbiology, personal hygiene, product temperatures and proper storage - "simple, basic information that people working with **food** really ought to know," he explained.

Wegman told the Speaks audience that FMI's **food** safety task force, of which he is a member, endorses the Hazard Analysis Critical Control...

...of our industry need to apply this discipline to all perishable products."

Wegman said the **HACCP** system brings **food** safety controls to the next level by helping us identify where **contamination** is most likely to occur and developing controls for those vulnerable points. And the nice...

...itself by reducing spoilage and shrink."

He also said the task force is promoting the **Food** and Drug Administration's **Model Food** Code, "but the code is the size of a telephone book. We need to break...

...sure the right information reaches the right people," Wegman said.

According to Wegman, FMI's **food** safety task force was formed "to develop a comprehensive, **model food** safety program for supermarkets, to heighten the awareness and level of responsibility of retailers and...

...and wholesome as possible.

"Outside the store, we're looking to other parts of the **food** system that affect safety before products reach us, including more rigorous buying specifications and ensuring...

...through public education to deliver key messages to increase their knowledge and personal responsibility for **food** safety. We're beginning that effort with research to identify the effective messages and mediums consumer confidence in the ability of supermarkets to provide safe **food** has increased to 84%, according to FMI's 1996 Trends survey, compared with 77% a...

...is the highest confidence level since 1989, when the level was 89%. "Then we had **food** safety scares involving the pesticide Alar and the alleged tampering involving Chilean grapes, and confidence...

...safe, the 1996 survey found 16% of respondents said they are relying more on their **food** stores to ensure that products are safe, up from 8% in the 1995 survey, Sansolo...

COMPANY NAMES: Wegmans **Food** Markets Inc...
INDUSTRY CODES/NAMES: **FOOD** **Food** , Beverages and Nutrition...
DESCRIPTORS: **Food** Marketing Institute...

... **Food** --
...PRODUCT/INDUSTRY NAMES: 2000000 (**Food** & Kindred Products)
19960513

17/K/23 (Item 9 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

05569933 SUPPLIER NUMBER: 11436000 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Biotechnology for safe and wholesome foods.
Morris, Charles E.
Food Engineering International, v16, n5, p67(5)
Oct, 1991
ISSN: 0148-4478 LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
WORD COUNT: 2074 LINE COUNT: 00177

... Research Laboratories in Vlaardingen, The Netherlands, to review recent developments and discuss new directions in **food** biotechnology. Symposium theme: "Biotechnology For Safe & Wholesome Foods." Highlights follow.

|DESIGNER OILS'

Because it is widely recognized that saturated fatty acids correlate with serum cholesterol and coronary heart disease, many **food** processors are replacing existing fats (such as milk fat) with less saturated alternatives (such as...

...shelf life, focusing interest on modifying oilseed crops via classical breeding or genetic engineering to **produce** oils with specific functionalities.

The limitations of conventional breeding can be bypassed by using cloned genes to create genetically-modified plants that **produce** "designer oils" with fatty-acid compositions tailored to specific applications, said Dr. C.R. Sommerville...

...the relative amounts of these fatty acids. Using mutants of the small mustard Arabidopsis (a **model** organism because of its small genome) defective in the enzyme glycerol-3-P-acyltransferase, significantly...

...structured lipids, however, is "some distance off," Sommerville cautioned, and current research aims at restructuring **vegetable** oils for more valuable non- **food** applications.

Production of structured lipids, however, is "some distance off," Sommerville cautioned, and current research aims at restructuring **vegetable** oils for more valuable non- **food** applications.

NON-DAIRY FERMENTATIONS

Starter organisms used to **produce** flavors in fermented foods are essentially of two types: those of limited competitiveness but effective...

...developed for genetically-engineering Lactococci, on the other hand, have often required substantial modifications.

CHEESE **HACCP**

Although of low probability, a wide range of spoilage phenomena -- caused by unwanted products of...

...should be not in trying to control secondary flora but in monitoring the process via **HACCP** (Hazard Analysis Critical Control Points), said Dr. P. M. Klapwijk of Unilever. "As public health...

...should have little to add here," said Klapwijk. But "biotechnology may well fit into the **HACCP** approach by offering monitoring options which can be used to guard critical control points (CCPs)." (See table.)

"After pasteurization and the introduction of primary flora (starter cultures), all **contamination** should be prevented by physical methods." A combination of proper raw materials, pasteurization and good...

...safe but competitive organisms.

MICROBIOLOGICAL QA

Although physio-chemical monitoring systems are currently preferred

for **HACCP** , there is a need for simple and rapid microbiological tests which can be adapted to...

...and polymerase chain reactions (PCRs). Not many of these have been used to date in **food** plants, however. The reasons, according to ...enzyme immunoassay can detect as few as five Salmonella cells.

NATURAL PRESERVATIVES

Lactic-acid bacteria **produce** two major classes of bacteriocins (antimicrobial proteins): those cidal to a narrow range of target...

...canned foods.

Pediocin PA-1, produced by the Pediococcus acidilactici, has been isolated from fermented **meat** by Unilever subsidiary Microlife Technics (Sarasota, FL) and is effective in high-moisture foods such...

...systems other than lactic-acid bacteria (Apidaecins) show promise inhibiting gram-negative organisms.

CHILLED-FOODS **MODEL**

Dr. Par Olsson of the Swedish Institute for **Food** Research (Goteborg) discussed results to date of research aimed at predicting the shelf life of...

...distribution costs. If quality can be estimated with reasonable accuracy at any stage in the **distribution chain** , said Olsson, the distribution center may be able to improve quality control and eliminate risks...

...using altered frequencies, and employing trucks with different types of equipment.

A computerized predictive-microbiology **model** has been developed. Tests incorporate the Lifelines integrator with bar code containing a polymer compound...

...of lactic-acid bacteria; and 2) production of strains meeting the specific requirements of the **food** and feed industries.

"The EC has a clear mandate to strengthen its scientific and technological...

...become more competitive at the international level," Aguilar concluded.

Critical Control Points (CCPs) In Cheese **HACCP**

Raw Milk	CCP2
Holding	CCP2
Bactofugation	CCP2
Pasteurizing	CCP1
Processing	CCP2
Handling Cheesewheels	CCP2

Cutting...

...international giant with 70 billion Dutch guilders in total sales, half of which are in **food** , is captured in the steel sculpture dominating the entrance to the Unilever Research Laboratories at...

CAPTIONS: Critical control points (CCPs) in cheese **HACCP** . (table)

INDUSTRY CODES/NAMES: **FOOD** **Food** , Beverages and Nutrition
DESCRIPTORS: **Food** --...

... **Food** research...

... **Food** engineers
19911000

17/K/24 (Item 10 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

04918268 SUPPLIER NUMBER: 10655719 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Assuring a healthy food supply: a case for fundamental reform of regulatory programs.
Hardy, Stuart B.

American Review of Public Administration, v20, n4, p227(17)
Dec, 1990
ISSN: 0275-0740 LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
WORD COUNT: 7508 LINE COUNT: 00631

Assuring a healthy food **supply: a case for fundamental reform of regulatory programs.**

TEXT:

...a steady procession of have alarmed consumers and drawn attention to the surveillance well Publicized **food** scares-some more perceived than real-that and inspection activities of various regulatory programs. Investigations...

...shortcomings in program design and execution. Many problems are deeply rooted in a history of **food** regulation too often characterized by hasty, piecemeal solutions to health threats that have arisen in one **food** sector or another. Less attention has been paid to examining potential hazards in the **food** supply as a whole and directing limited federal resources toward areas where risks to health...

... corresponding benefit to public health.

There is a pressing need to harmonize and modernizing the **food** regulatory system as a whole. A growing number of policymakers, consumer groups and industry leaders...

...of a science-based set of regulatory principles known as Hazard Analysis, Critical Control Points (**HACCP**). These principles, applicable to every link in the **food** production, processing and **distribution chain** , focus on the process rather than the product, and seek to control potential hazards at...

...the plant, in the market and elsewhere. However, the introduction of science based systems of **food** safety assurance will pose numerous challenges to the federal, state and local agencies charged with **food** regulation. Moreover, since **HACCP** transfers much of the burden of safety assurance onto the industry itself, its success ultimately depends on the good faith commitment of the **food** industry.

The lively dialogue now taking place in the **food** regulatory arena has widespread implications for other sectors of the economy where government safety assurance...

...article is to examine gaps, inconsistencies and conflicts in current federal and state systems of **food** safety assurance, identify areas where laws and regulations may not have kept pace with science...

...ongoing methods of harmonization and modernization. The scope is restricted to human health and the **food** supply. it does not extend to economic and market regulatory issues such as misbranding, fraudulent claims or standards of identity.

Food safety regulation is of keen interest because consumers are increasingly aware of the linkage between...

...of government. They expect not only to be protected from hazards, but also want a **food** supply that will promote health and longevity. At the same time, the **food** supply itself is diversifying at the rate of 2,000 new products per year and...

...technically more complex as new ingredients, additives and processing techniques are introduced. The revolutions in **food** packaging and marketing, in particular, are posing new challenges to **food** safety assurance.

Meanwhile, the competition for public resources, at all levels of government, is becoming more intense and regulators find themselves with limited dollars and a vastly more complex **food** supply to monitor. The **Food** and Drug Administration, for example, has lost more than ten percent of its total workforce...

...scarce resources as far as possible without jeopardizing the ability of regulators to monitor the **food** supply. This daunting task has prompted

policymakers to consider new methods of surveillance and safety...

...local, state and federal agencies.

A Brief History

Until this century, the local nature of **food** production and distribution meant that **food** safety was principally the responsibility of states and their subdivisions. This responsibility has moved to...

...become increasingly national.

In the early years of this century, well publicized abuses in the **meat** packing industry prompted Congress in 1906 to enact the Federal **Meat** Inspection Act mandating Agriculture Department inspection of slaughtering and packing plants doing business across state lines. The same year Congress enacted the Pure **Food** and Drugs Act giving the Agriculture Department broad jurisdiction over **food** in interstate commerce. The essential goal of both landmark statutes was to prevent the adulteration of foods by the presence of filth, poisons, or decomposed animal or **vegetable** substances. in 1930, the McNary-Mapes Amendment to the Pure **Food** and Drugs Act set quality standards for canned foods, and in 1938, the Federal **Food** ,, Drug and Cosmetic Act gave the Department of Agriculture important new powers to engage in economic regulation and set legally enforceable **food** standards, affirmative labeling requirements and better enforcement of sanitary conditions in **food** preparation and packing.

Initially, Congress gave the Department of Agriculture lead responsibility for **food** safety regulation. These important mandates were assigned, in due course, to an agency that become known as the **Food** and Drug Administration (FDA). Not until 1940 was FDA transferred out of the Department of...

...Egg Products Inspection Act.

In 1958, Congress required pre-market approval of ingredients added to **food** and shifted to industry the burden of proving an ingredient safe. This **Food** Additives Amendment of 1958 included the now famous Delaney clause prohibiting any substance "found to...

...Additive Amendments of 1960 and the Animal Drug Amendments of 1968.

In 1967, the Wholesome **Meat** Act amendments brought the Federal **Meat** Inspection Act into closer conformity with the Federal **Food** , Drug and Cosmetic Act and required state **meat** inspection programs to be at least equal to" federal standards. In 1986, the Federal **Meat** Inspection Act was again amended to give the Agriculture Department authority to move beyond continuous inspection of post-slaughter **meat** processing facilities.

Federal regulation of pesticides dates back to 1947 when synthetic organic pesticides were...

...EPAS pesticide program is also responsible for carrying out the pesticide provisions in the Federal **Food** Drug and Cosmetic Act. This Act requires EPA to set limits or tolerances specifying the amount of pesticide residue that can be legally present in or on **food** sold in interstate commerce. Currently, there are about 8,500 tolerances for **food** use pesticides.

The history of federal **food** regulation represents an evolution toward more sophisticated and comprehensive surveillance of the **food** supply. Nevertheless, regulatory fragmentation, gaps, inconsistencies and even conflicts continue to exist. This is perhaps...

...programs have been created piecemeal and over many decades in response to problems in specific **food** sectors. For example, significant **food** safety mandates have been assigned by Congress over the years to nine federal agencies lodged...

...the District of Columbia, the four overseas territories,[1] and their subdivisions are involved in **food** safety regulation in one way or another. Total state dollars and personnel dedicated to **food** safety is roughly equivalent to the total level of federal resources in this broad area...

...State programs are typically lodged in health and agriculture agencies. Forty-five states have enacted **food** provisions based on the Federal **Food**

, Drug and Cosmetic Act. This statute, together with FIFRA, the Federal **Meat** Inspection Act, the Poultry Products Inspection Act and the Egg Products Inspection Act, assign states...

...of jurisdiction and authority are unclear. Moreover, in some situations, such as pesticide residues in **food** , states have clear legal authority to establish regulatory requirements in addition to those imposed by...

...employees to carry out inspections in federally inspected plants.

Table I

Federal Agencies with Significant **Food** Safety Mandates

Independent Agency
U.S. Environmental Protection Agency
Cabinet Departments
1. Department of Health and Human Services
Food and Drug Administration
(**food** animal drugs and feeds and all foods except **meat** , poultry, eggs, wine and liquor)
Public Health Service Foodborne illness monitoring)
2. Department of Agriculture
Agricultural Marketing Service (eggs)
Animal and Plant Health Inspection Service
(live **food** animals)
Federal Grain Inspection Service
(grain and oilseed crops)
Food Safety Inspection Service
(**meat** and poultry)
3. Department of Commerce
National Oceanic and Atmospheric Administration
National Marine Fisheries Service...

...liquor)

In one area, state and federal agencies operate parallel programs. Twenty-eight states have **meat** and/or poultry inspection programs that are equal to" federal programs in terms of standards and surveillance. In these states, **meat** and poultry firms whose products are marketed exclusively within state borders, are given the option...

...which further assures nationwide regulatory uniformity. The milk sector may serve as something of a **model** for other **food** sectors. For example, FDA and states involved in seafood regulation have recently established the interstate Shellfish Sanitation Conference along lines somewhat similar to NCIMS, and a similar conference (Conference for **Food** Protection) has been organized and is active in other **food** sectors.

All state and federal **food** regulatory programs share a basic objective of protecting consumers from foodborne illness and assuring a wholesome **food** supply. However, the way regulators go about this task, the methods they use and the...

...A notable example of differing regulatory approaches is provided by USDA and FDA. USDA's **Food** Safety inspection Service (FSIS), for example, carries out mandatory inspection of all **meat** and poultry slaughtering and processing facilities. The agency employs more than 7,300 inspectors who417 million. in contrast, FDAS Center for **Food** Safety and Applied Nutrition is responsible for assuring the wholesomeness of all foods in interstate commerce except **meat** , poultry, eggs and liquor. Altogether, FDA employs about 800 inspectors in the field who spend...
...percent of their time covering a total inventory of some 67,000 plants, and other **food** operations. These inspectors are supported by approximately 140 laboratory personnel in 19 field labs. The...

...different, as mandated by law. There is an intensity of regulation and surveillance in the **meat** and poultry sector that is unmatched anywhere else in the **food** system for reasons that have more to do with history than with science.[3] Before...

...FDA regulation is entirely different. In particular, the frequency of FDA inspections very widely from **food** sector to **food** sector. In one sector, medicated feed mills, the frequency of inspection is mandated by

law...

...different regions of the country.
FDA inspectors are authorized to cover every link in the **food** chain including farms, warehouses, ports of entry, processing plants, transportation vehicles, restaurants and supermarkets. High...

...plant construction and design, equipment, sanitary conditions and methods used to control biological or chemical **contamination** . They may take samples for further tests, and must meet with the plant manager at...
...inspectors must have a bachelors degree with at least 30 hours of course work in **food** science.
FDA attempts to concentrate resources on areas where risk is greatest, such as certain...

...carrier of pathogens, natural toxins (especially ciguatoxin and scombrotoxin) and parasites, not to mention chemical **contamination** .[6] According to the General Accounting Office (1988), FDA samples less than 1% of domestic...

...they are carefully targeted on potential problem areas. Nevertheless, the contrast between seafood regulation and **meat** /poultry/egg regulation could hardly be greater.
There is one important characteristic that both FDA...

...effectiveness as watchdogs of the public health. The adversarial relationship is especially pronounced in the **meat** and poultry sector where federal and state inspectors have the authority to shut down an...

...if the adversarial relationship is eliminated.
Conflicting Cancer Policy
The regulation of carcinogens in the **food** supply is another area fraught with conflict and inconsistencies. Career policy remains in the spotlight because of the public misperception that pesticide residues in **food** pose a significant risk of cancer in humans even though the scientific evidence indicates that...of pesticides residues is negligible.[7] Nevertheless, cancer policy is a major factor in total **food** regulation.
in 1958, when Congress was debating the inclusion of **food** additive provisions to the Federal **Food** , Drug and Cosmetic Act, Rep. Charles Delaney (D-NY) inserted the now famous clause: "No...

...it is found, after tests which are appropriate for the evaluation of the safety of **food** additives, to induce cancer in man or animal".[8]
This language means, in practice, that no substance, in any amount, may be intentionally added to **food** if it has been shown to cause cancer in animal tests. Consequently, Delaney, unlike all...

...attempted to regulate some measure of flexibility into the zero risk standard. With respect to **food** and color additives, FDA's "constituents policy" holds that a constituent of an additive may...

...suspected carcinogens and because the ability to detect ever smaller amounts of a chemical in **food** has far out paced the ability to assess accurately the effects of tiny residues on...

...pointed out (Kennedy, 1989). Polling data indicate that the public's biggest concern about the **food** supply is the fear of cancer-causing pesticide and animal drug residues. These fears are...

...Congress where pesticide residues, in particular, get far more attention than other threats to the **food** supply. Health professionals, on the other hand, agree overwhelmingly that the greatest foodborne health risks...

...enteritidis and Listeria monocytogenes. If the health professionals are correct, there are widespread misperceptions about **food** safety In either case, regulators are put in the difficult position of being forced to...

...them are more imagined than real.

Exceptions to Delaney

Significantly, not all substances added to **food** are subject to the Delaney zero cancer tolerance standard. Delaney was designed to be prospective...

...use today.

In addition to prior sanctioned and GRAS substances, there are other categories of **food** substances not subject to Delaney. Naturally occurring chemicals and substances which cannot be avoided through good manufacturing practices are exempt. Aflatoxin, a potent animal carcinogen, is allowed to enter the **food** chain through the latter category. [11]

Last, but not least, the huge category of raw...

...cancer causing pesticide, for example, can be allowed on or in a fresh fruit or **vegetable** if it has a tolerance set by EPA under Sec. 408 of the Federal **Food** Drug and Cosmetic Act or if EPA has granted an exemption from a tolerance. EPA...

...setting process under Sec. 408 (raw agricultural commodities) collides with the requirements of Sec. 409 (**food** additives) as explained in detail in a landmark report of the National Academy of Science...

...years later, contains the Delaney zero cancer risk standard. The conflict occurs when a raw **food** commodity, legally containing a trace residue of a potentially carcinogenic chemical, is further processed in... ever before in our history. Associations of state regulatory officials, such as the Association of **Food** and Drug Officials (AFDO), have made encouraging progress in harmonizing different state programs and developing **model** state laws and regulations.[14] At the same time, federal officials are relying more and...

...area of conflict involves the regulation of pesticide residues in or on foods. The Federal **Food** , Drug and Cosmetic Act directs EPA to set such tolerances or grant exemptions. However, under...

...shelves in one state while they continued to be sold in others. Since then, other **food** pesticide residue conflicts have occurred - most recently involving daminozide (Alar) on apples and apple products...

...will likely occur given the fact that some 300 chemicals are used in and around **food** , that these chemicals are subject to on-going review for health effects, and that methods...

...a vote of no confidence in federal agencies. It requires clear and reasonable warning" for **food** products that contain substances known to the state to cause cancer" even though these chemicals are approved for **food** use by federal agencies. This warning requirement may mean that products sold in California containing...

...laws are now under consideration in at least three other states.[15]

Reconciling Differences Through **HACCP** Principles

It has been shown that the **food** safety assurance system, at both state and federal levels, is a patchwork of widely differing...

...many decades. There is a growing recognition among regulators, health professionals, consumer advocates and the **food** industry itself, that the current system is not equal to the challenges posed by today's rapidly proliferating **food** supply.

For example, regulators are ill equipped to detect and destroy microbial **contaminants** (bacteria, viruses and parasites) because diagnostic testing is performed infrequently and **contaminated** products may pass into commerce before test results are known. Similarly, in **meat** and poultry processing plants, scarce agency dollars are consumed by labor intensive continuous inspection methods...

...one of harmonizing and modernizing methods of regulation by applying "hazard analysis, critical control point" (**HACCP**) principles uniformly throughout the entire **food** chain.

HACCP " is a science-based safety assurance methodology that

requires the identification and monitoring of all points in the **food** chain where critical hazards may arise. Specifically, these principles are as follows:

1 .Assessment of...

...associated with growing, harvesting, raw materials and ingredients, processing, manufacturing, distribution, marketing and preparation of **food** .

2. Determination of the critical control points required to control the identified hazards.

3. Establishment...

...corrective action taken in response to deviations.

7. Establishment of procedures for verification that the **HACCP** system is working correctly.[16]

The **HACCP** concept was developed three decades ago in preparation for the first U.S. maned space flight, and further refined in the 1970's in response to a lethal **botulism** outbreak traced to canned soup. At present, **HACCP** is required only in low acid canned **food** and acidified **food** processing facilities, although Congress may soon mandate **HACCP** criteria for the entire seafood industry.[17] Meanwhile, FDA, USDA and the National Marine Fisheries Service are all developing new regulations based on **HACCP** methodology[18] and some elements of the **food** industry are also moving in this direction on a voluntary basis.[19]

Implementing **HACCP** Principles: Methods and Compliance

In practice, **HACCP** puts most of the burden of safety assurance on industry Its effectiveness depends on industry's willing acceptance of this responsibility While some major firms are voluntarily adopting **HACCP** systems, other sectors of the **food** industry may not be prepared or inclined to accept the responsibility.

Practical experience with **HACCP** systems gleaned from the low acid canned **food** industry and elsewhere strongly suggests that implementation and maintenance of these programs can be difficult...

...ways of doing business, and are therefore difficult to implement.

With respect to owner operated **food** establishments, such as farms or small retail firms, several steps may be taken to facilitate implementation and maintenance of **HACCP** programs. Trade and grower associations may play a major role in assisting members to operate **HACCP** programs.[20] Grower financed commodity marketing orders, such as those for fruits and **vegetable** , may need to be amended to include health related standards.

Similarly, state and federal regulators...

...also alter their methods and operational philosophy Their role is no longer to inspect individual **food** products but rather to verify the effective design and operation of the total safety assurance...

...must also be provided with timely access to plant records.

Conclusion

The process of introducing **HACCP** principles into the regulatory framework is likely to be a gradual, evolutionary process, and **HACCP** systems may coexist with traditional inspection methods during a lengthy transition period. There are several reasons for this. For one thing, it may take years to develop and implement specific **HACCP** criteria for those links in the **food** chain dominated by small scale producers. A huge amount of education will be needed before...

...will provide a period of grace for regulatory personnel, such as the large force of **Food** Safety Inspection Service line inspectors, who may lack the skills or inclination for retraining.

However gradual, the **HACCP** process appears irreversible. The enormous size, diversity and sophistication of the U.S. **food** industry, and the proliferation of new products, makes traditional surveillance methods increasingly ineffective. The only way to assure healthy and wholesome **food** is to require the industry itself to take on far more responsibility for safety assurance...

...2] Perhaps the best single source of information on state spending and personnel resources in **food** safety can be found in May (1989).

[3] The legacy of Upton Sinclair's The Jungle is still evident (Sinclair, 1981). The **meat** and poultry system was originally designed to prevent the abuses Lewis called attention to at...

...labor intensive system of visual inspection in which inspectors, often with only limited training in **food** science, stand at carcass production lines and look for signs of disease and unwholesomeness such...

...on the inspectors sense of sight, touch and smell. It cannot detect microbial or chemical **contamination** . Microbial **contamination** , in particular, is the primary human health hazard present in the **food** supply today. FSIS has attempted to keep abreast of emerging threats to the **meat** and poultry supply by increasing residue testing and monitoring and adopting a plant-wide approach...

...at least once every two years.

[5]States have varying degrees of power of seize **food** , detain equipment, and close facilities, often without a court order. FDA sometimes relies on a...7]in August, 1988, scientists representing eighteen professional societies met to evaluate risks to the **food** supply. The participants concluded that pesticide residue risks are relatively minor and far less import that microbiological hazards, naturally occurring toxins, and environmental **contaminants** . See institute of **Food** Technologists (1989).

[8]21 U.S. Code 348 (c)(3).

[9]FIFRA, the Toxic Substances...

...like aflatoxin, may pose a greater cancer threat than synthetic chemicals such as pesticides and **food** and color additives. Consumers may ingest in their diets at least 10,000 times more...

...current standards in nine years.

[14]AFDO also includes federal regulators. Other organizations of state **food** regulators are the Association of American Feed Control Officials, the Dairy Division of the National Association of State Departments of Agriculture, the Association of State **Meat** and Poultry Directors, the Association of Fruit & **Vegetable** Inspectors and Standardization Agencies, the Association of American Pesticide Control Officials, the Association of American Plant **Food** Control Officials, the Association of American Warehouse Control Officials, the Association of Official Seed Analysts...

...National Assembly of Chief Livestock Health Officials, the National Plant Board, and the Conference for **Food** Protection.

[15]As of May 1990 other states considering similar legislation are Massachusetts, New Jersey...

...committees.

[18]For example, USDA has established an advisory committee to help the agency make **food** regulations consistent with **HACCP** principles, and FDA is incorporating **HACCP** criteria into their "good manufacturing practices" handbooks.

[19]Several **food** trade associations, such as the National Fisheries Institute, are sponsoring workshops and seminars to help member firms voluntarily implement **HACCP** programs.

[20]several farm and **food** trade organizations including the National Cattlemens Association, the **Food** Marketing Institute, the United Fresh Fruit and **Vegetable** Association, among others, are now conducting **HACCP** workshops for their members.

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Stuart B. Hardy is Manager of the **Food** , Energy and Natural Resources Policy Division of the National Chamber of Commerce in Washington, D.C. where he is responsible for legislation, regulation and trade policy affecting the U.S. **food** and agriculture industry. A registered lobbyist and frequent witness before Congressional committees, Dr. Hardy served on the staff of Sen. Bob Dole (R-KS) and represented an association of state **food** regulatory agencies before joining the Chamber in 1984. He holds a Ph.D. degree in...
CAPTIONS: Federal agencies with significant **food** safety mandates. (table)

DESCRIPTORS: United States. **Food** and Drug Administration...

... **Food** adulteration and inspection...

... **Food** supply
19901200

17/K/25 (Item 1 from file: 636)
DIALOG(R)File 636:Gale Group Newsletter DB(TM)

04127768 Supplier Number: 54197540 (USE FORMAT 7 FOR FULLTEXT)
Senators criticize FDA's Seafood HACCP **, import inspections at budget hearing.**
Food Chemical News, v41, n5, pNA
March 22, 1999
Language: English Record Type: Fulltext

Document Type: Newsletter; Trade
Word Count: 950

Senators criticize FDA's Seafood HACCP , import inspections at budget hearing.

... Henney was on the defensive March 16 as Democratic senators directed criticism at FDA's **food** import and seafood **HACCP** inspection programs during a Senate Appropriations agriculture subcommittee hearing.

While senators also heard from USDA...

...s Jeffrey Koplan on the administration's fiscal 2000 budget request for the president's **Food** Safety Initiative, most questions and criticisms were aimed at Henney. Bolstered by the latest news from CDC about reductions in Salmonella and Campylobacter illnesses, the senators suggested that USDA's **meat** and poultry **HACCP** program should be viewed as a **model** for FDA to follow (See **Food** Chemical News, March 15, Page 27).

Some of the toughest questions came from Sen. Tom...

...federal standards would hand U.S. authorities more leverage to demand that foreign countries meet **food** safety standards for fresh fruits and vegetables.

"The absence of domestic regulatory standards for fresh...

...by setting federal standards," said Harkin, who pledged his support for full funding for the **Food** Safety Initiative.

But while FDA put out voluntary guidelines for good handling practices of agricultural commodities, USDA set mandatory standards for **meat** and poultry so that other countries must meet those standards to export here, Harkin explained.

In response, Joseph Levitt, director of FDA's Center for **Food** Safety and Applied Nutrition, insisted that there were gaps in the underlying science about how...

...fruits and vegetables, how to detect them once they get there, and how to prevent **contamination** throughout the **distribution chain** . "So science is at the voluntary guidance stage," he said.

Harkin responded that a bill requiring mandatory washing standards and clean water for growing **produce** , and banning warehouses where rats and birds could **contaminate** products, would not be "too high scientifically."

Levitt again said there was not enough science...

...said. When asked what authority Henney would need to cover the ever-increasing number of **food** imports, she said added authority would be appreciated and that she would work with Dorgan on that.

Seafood **HACCP** under scrutiny

The industry's compliance record for the first year under seafood **HACCP** drew the attention of Sen. Richard Durbin (D-Ill.), who said consumer groups call the...

...of seafood firms found to have serious or critical deficiencies during the first year of **HACCP** , Durbin questioned the effectiveness of the new FDA program, and said USDA experienced a "radically different compliance rate during its first year."

USDA phased in its **meat** and poultry **HACCP** program, but FDA opted to include everyone from the smallest businesses to the largest seafood...

...a feasible approach of annual inspections. Also, only 5% were really violative of the seafood **HACCP** program, she said.

But with almost 40% of seafood plants not participating in the program...

...statutes.

Durbin, chief author of last year's bill that would have created a single **food** safety agency, chastised industry trade associations for issuing press releases spinning the presidential **Food** Safety Council's new report to say it did not recommend a single **food** safety official. The report includes a clear recommendation for one coordinated leader on **food**

safety, he said. But groups such as the National **Food** Processors Association and Grocery Manufacturers Association said the report "concludes the opposite. They should have a closer look at the report," he said, and not resist attempts to improve the **food** safety system.

On the issue of FSI funding, subcommittee Chairman Thad Cochran said it was...

...FSI" in the administration's budget request. While USDA funds a small amount of the **Food** Safety and Inspection Service's budget with FSI funds, FDA includes the basic funding of seafood **HACCP** in the interagency program.

He also asked when USDA's irradiation rule would be finalized...
...2000. Cochran raised questions about where consumer safety officers would be placed under USDA's **HACCP** program, and whether the agency's plan to redeploy inspectors from plants to the distribution...

...plans to continue coordinating with FDA and local inspectors through participation in the Conference for **Food** Protection.
INDUSTRY NAMES: BUSN (Any type of business); CHEM (Chemicals, Plastics and Rubber); **FOOD** (**Food** , Beverages and Nutrition)
19990322

17/K/26 (Item 1 from file: 35)
DIALOG(R)File 35:Dissertation Abs Online

01682336 ORDER NO: AAD99-16541
A MODEL **OF** FOOD **SAFETY FOR A** FOOD **PROCESSING, DISTRIBUTION, AND WAREHOUSING CENTER**
Author: HEADY, DOTTY
Degree: ED.D.
Year: **1998**
Corporate Source/Institution: SPALDING UNIVERSITY (0965)
Source: VOLUME 59/12-B OF DISSERTATION ABSTRACTS INTERNATIONAL. PAGE 6132. 148 PAGES

A MODEL **OF** FOOD **SAFETY FOR A** FOOD **PROCESSING, DISTRIBUTION, AND WAREHOUSING CENTER**
Year: **1998**
Descriptors: AGRICULTURE, **FOOD** SCIENCE AND TECHNOLOGY ; HEALTH SCIENCES, PUBLIC HEALTH ; BIOLOGY, MICROBIOLOGY

...fascination for this writer about the connection between the tiny, invisible contact points that become **contamination** points, in the **food** chain process, which cause members of the human race to become ill, and even sometimes, to die. This study will be examining the general **food** safety in a processing plant and how the use of common sense and the applied principles of Hazard Analysis Critical Control Points (**HACCP**) can develop a **contamination** -free process flow. People who work in processing plants and distribution centers are just that—people. The handling of **food** is always a possible source of **contamination** . Many **food** processing workers know sound hygienic principles of **food** protection and practice them, both at home and at work. There are however, many **food** processing workers, especially newly hired workers, who do not know or appreciate the need for...

...President of the United States has recently recognized this fact. To protect the nation's **food** supply, on August 25, 1998, President William J. Clinton signed an executive order creating a council to oversee **food** safety, a task currently handled by a patchwork of federal agencies that have created a...

...the education and prevention activities that this work addresses in the form of a working **model** or modeling techniques for one important segment of the long chain of the **food** supply; **food** processors and distribution centers.

This study will demonstrate how every person at each step in...

...foodborne illness and foodborne injury by following simple procedures. By modeling the steps outlined, the **food** processor and distribution centers can be assured that only safe products enter the **food** chain. The governmental regulators tell the processors that they must comply with the rules, laws and regulations to keep the nation's **food** supply safe but do not tell the **food** processors <italic>how</italic> to go about doing this to comply with the rules, laws...

...an appropriate educational module to assure that the final outcome of each step in the **food** processing and **distribution chain** , results in safe **food** .

17/K/27 (Item 1 from file: 180)
DIALOG(R)File 180:Federal Register

DIALOG Accession Number: 02496733 Supplier Number: 990700409
Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels
Volume: 64 Issue: 128 Page: 36516
CITATION NUMBER: 64 FR 36516
Date: TUESDAY, JULY 6, 1999

...AGENCY: **Food** and Drug Administration...

...Center for **Food** Safety and Applied Nutrition

TEXT:
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
21 CFR Parts 16, 101, and 115
(Docket No. 99N-1307)
RIN...
... Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels
Agency: **Food** and Drug Administration, HHS.

Action: Preliminary regulatory impact analysis and initial regulatory flexibility analysis.

Summary: The **Food** and Drug Administration (FDA) is publishing both the preliminary regulatory impact analysis prepared under Executive...

...intended to ensure that consumers will have the information necessary to protect themselves from eggs **contaminated** with SE and to ensure that eggs will be held at retail at temperatures that...

...by September 20, 1999.

Addresses: Submit written comments to the Dockets Management Branch (HFA-305), **Food** and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified...
...brackets in the heading of this document.

For Further Information Contact: Clark Nardinelli, Center for **Food** Safety and Applied Nutrition (HFS-726), **Food** and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-8702.

Supplementary Information...

...Refrigeration Provision Only
4. Refrigerate at 5 deg. C (41 deg. F)

5. Implement a **HACCP** -Style System for Shell Eggs
6. In-Shell Pasteurization
7. Longer Compliance Periods
8. Limit...

...1. Establishments
2. Products
E. Benefits
1. The Shell Eggs and Egg Products Risk Assessment **Model**
2. Cases of Salmonellosis Prevented
3. Health Benefits from Preventing Salmonellosis
4. Total Health Benefits... million. One comment suggested allowing existing safe handling labels. Several comments advocated some form of **HACCP** for shell eggs. Comments regarding the regulatory impact of the proposed rule are addressed below...

... consumers, and should reduce the illnesses and deaths that can occur from consumption of eggs **contaminated** with SE.

Private markets operate within the framework of legal institutions. The tort system of...

...to the specific product of a specific producer.

In most instances, consumers experiencing illness from **food** consumption do not recognize the illness as foodborne or are unable to link the illness to consumption of a particular **food** . This inability to connect illness and **food** exists because many symptoms do not occur immediately after consumption of the product. The proposed...

... held at appropriate temperatures at retail and consumers are put at greater risk from SE- **contaminated** eggs. The increased risk resulting from SE- **contaminated** eggs that are not held at appropriate temperatures in retail establishments can lead to involuntary...
... occurrence of illnesses--because of the long time lapse between the purchase of the SE- **contaminated** eggs and the onset of SE-related illnesses.

By requiring safe handling statements, the proposed rule will provide information about the potential adverse health effects of SE- **contaminated** eggs. The information will persuade some consumers to change potentially risky handling practices and thereby...

... is not complete if people do not know the potential health risks associated with SE- **contaminated** eggs. The lack of information places consumers, especially the young, the elderly, and persons with...

... by SE in shell eggs. State and local governments that adopt and enforce the 1999 **Food** Code as issued by FDA will meet the goals of the proposed refrigeration rule.
Adopting the **Food** Code as issued by FDA will also reduce undercooking of eggs in restaurants, which will accomplish part of the goals of the proposed labeling provision. The 1999 **Food** Code requires raw shell eggs to be cooked 15 seconds at 63 deg. C (145...

...to be cooked 15 seconds at 68 deg. C (155 deg. F). Because the 1999 **Food** Code has not been adopted everywhere and because billions of shell eggs are prepared in...

...bring about the goals of the proposed rule. If victims could sue sellers of SE- **contaminated** eggs for damages, the incentives to retailers to eliminate SE from shell eggs would increase...

...Furthermore, the effectiveness of litigation is questionable because the link between the consumption of SE- **contaminated** eggs and illnesses may be difficult to establish for outbreaks and is nearly impossible to...

...2. Labeling Provision Only
The agency could require that egg cartons contain the instructions to

food handlers to "keep refrigerated", "cook ... Requiring the safe handling label alone would place the burden of reducing risk from SE- **contaminated** eggs solely on **food** handlers, which includes consumers, restaurants, and institutions. If **food** handlers follow good sanitation practices and eggs are cooked thoroughly, the risk of salmonellosis from SE- **contaminated** shell eggs can be virtually eliminated. FDA believes that the safe handling label will improve...

... 50 deg. F) slows the growth of SE. Because the level of Salmonella that initially **contaminates** eggs is usually low, refrigeration following laying should keep the numbers of pathogens low until...

... deg. C (41 deg. F), the internal temperature for potentially hazardous foods in the 1999 **Food** Code. Although current studies show Salmonella growth at ambient temperatures under 50 deg. F is...

...the labeling and the 7.2 deg. C provisions would take effect.

5. Implement a **HACCP** -Style System for Shell Eggs

The agency could require that a Hazard Analysis and Critical Control Point (**HACCP**) system be implemented at any or all levels of the shell egg production and **distribution chain** . In order to match the coverage of the proposed rule, the **HACCP** -style rule would have to be limited to the same set of establishments covered by the safe handling label. The advantage of a full farm-to-table **HACCP** is that it could eliminate, reduce, or control SE and other hazards at the source...

... and remedial steps to eliminate SE from shell eggs is incomplete. FDA believes that a **HACCP** -like program, possibly including in-shell pasteurization, is currently not feasible. However, FDA is evaluating whether a **HACCP** -like program in the future may be necessary to further ensure the safety of eggs...

... some consumers to erroneously believe that other safety measures, such as refrigeration and avoiding cross- **contamination** , might no longer be necessary.

Because pasteurization eliminates competing microorganisms, recontamination after pasteurization might lead...retail establishments, institutions, and homes is reduced by 1 percent, the USDA SE risk assessment **model** generates about a 0.5 percent decrease in the number of illnesses.

D. Coverage

1...

...Handling C (45 deg. F

Establishment	Labeling	)
Grocery stores	No	Yes
Restaurants	No	Yes
Health **food** stores	No	Yes
Roadside stands	Yes	Yes
Convenience stores	No	Yes
Prisons	No	Yes

Nursing...

... reducing the incidence of SE-related illness. FDA will estimate health benefits with the following **model** of marginal benefits (MB):

MB = R x M x V

where: -

R = the baseline risk...

...medical expenditures.

The refrigeration and labeling provisions will reduce but not eliminate the consumption of **contaminated** shell eggs. Requiring refrigeration at all retail outlets and requiring labeling that states that the...

... of data that have become available since the completion of the final version of the **model** , but the analysis closely followed that of the USDA SE risk assessment team.
FDA estimated...of the health cost per illness.

1. The Shell Eggs and Egg Products Risk Assessment **Model**
The USDA's Salmonella Enteritidis Risk Assessment uses a farm-to-table **model** of the production and consumption of eggs. The **model** consists of five parts: (1) Egg production, (2) shell egg processing and distribution, (3) egg products processing and distribution, (4) **food** preparation and consumption, and (5) public health outcomes.

Because the proposed rule will not affect the number of shell eggs **contaminated** with SE, FDA did not directly use the first three parts of the **model** . FDA estimated the effects of the proposed rule by introducing the provisions of the proposed rule into the preparation and consumption part of the **model** and then calculating the changes in public health outcomes.

The presence of SE in the raw egg is not sufficient to ensure that people will become ill from eating **contaminated** eggs. If the eggs are continuously refrigerated from the time they leave the processor up...

... the time they are cooked, and if they are thoroughly cooked, then the risk assessment **model** predicts that the SE will not multiply before cooking and cooking will eliminate the surviving...

... USDA SE risk assessment estimated the number of illnesses with a full farm-to-table **model** . The first stage of the **model** estimated the number of infected eggs laid with a **simulation** that incorporated the estimates of the number of infected flocks and the likelihood of frequency of infected eggs in an infected flock. The next stage of the **model** took the estimated number of infected raw shell eggs and estimated the number of infected eggs likely to be consumed. The **model** followed the eggs through possible paths from the farm to the table. Depending on how...

...remain stagnant, multiply, or (if pooled) spread to other eggs. The last stages of the **model** used a dose- response function to estimate the number and severity of illnesses caused by SE in shell eggs. All stages of the **model** used computer simulations to generate ranges and distributions rather than point estimates. FDA generated a...
... the Microsoft Excel version of the Palisade@Risk(R) quantitative risk assessment software. The first **simulation** , shown in part a of Table 3 of this document, is the baseline result of the SE risk assessment team **model** . The second **simulation** is the baseline **model** with 95 percent rather than 90 percent probability that shell eggs are refrigerated at 7.2 deg. C (45 deg. F) in retail establishments and institutions. FDA modified the original **model** because the agency had more recent information (see the next paragraphs) on the number of...

...deg. F). Part b of Table 3 of this document presents the results of the **simulation** based on the more recent information.

Part c of Table 3 of this document presents...FDA simulated the number of SE illnesses not reported with a negative binomial distribution. The **simulation** calculated the total number of illnesses (reported and not reported) as: Number reported + Negative binomial...

... to the results of outbreak analyses for the years 1988 through 1992, eggs were the **food** vehicle in 64 percent of the SE outbreaks for which the **food** vehicle could be identified (Ref. 4). Therefore, FDA assumed

that 60 percent represented the maximum...
... to eggs. More than half of the SE outbreaks, however, did not have a known **food** vehicle. If outbreaks with unknown vehicles are added to the total, then eggs accounted for...

...372 12,548 17,175 48,594

Deaths 66 250 354 985

c. CDC Surveillance **Model**

Illnesses 63,884 189,599 191,511 319,275

Arthritis 1,330 5,533 5...

... of the proposed rules. For the refrigeration provision, FDA used the USDA SE risk assessment **model** (as modified by FDA) to determine the effects of eliminating virtually all temperature abuse in retail and institutional establishments. In the **simulation** of the **model** , the number of illnesses fell as the proportion of establishments assumed to be holding eggs...

... of changes in consumer behavior as a result of the USDA safe handling label for **meat** to estimate the effects of the safe handling label for shell eggs. The **Food** Marketing Institute (Ref. 5) found that 59 percent of shoppers were aware of the USDA safe handling labels for **meat** . Of those aware of the labels, 43 percent changed their behavior as a result of ...

... hands) to 41 percent (washing or disinfecting counters, cooking areas, and utensils after contact with **meat**).
The behavioral changes most similar to what the proposed rules aim to bring about for...

... in proper cooking of meats and the 7 percent increase in proper refrigeration. If the **meat** cooking and refrigeration results indicate the likely effects of the proposed label for eggs, then...

... 2 percent reduction in unsafe refrigeration practices implied by the survey results for the USDA **meat** handling labels accurately reflected people's practices in their home, (2) the results for home **food** handlers would hold for restaurant **food** handlers, (3) the results for the **meat** label would hold for egg labels, (4) the change in behavior would extend to raw... 1,007 consumers was reasonably representative (Ref. 5). The greatest uncertainty in extrapolating from the **meat** handling results is in assuming that the effects will hold for those products that contain...

...consume them also appears to be deeply ingrained among consumers.

The USDA SE risk assessment **model** treats proper cooking as a kill step for SE. Whatever the baseline, if undercooking falls...

...of refrigeration--by 5 percent.

In separate simulations, FDA used the USDA SE risk assessment **model** to estimate the effects of the labeling provision, the refrigeration provision, and the proposed rule combining the provisions. In another **simulation** , FDA estimated the effects of including a "sell by" date on the label or some...

...baselines. FDA first simulated the possible regulatory approaches in the modified USDA SE risk assessment **model** . The simulations generated distributions of the number of illnesses prevented by those approaches. The results...

... distribution of the number and severity of illnesses. No farm-to-table steps entered the **model** . The CDC surveillance **model** could not estimate how the illnesses occurred; the **model** only produced an estimate of the number of illnesses. Because the CDC surveillance baseline was not an

outcome of a **model** , FDA could not directly estimate effects with the surveillance baseline. Instead, FDA assumed that the...

... percentage effects. FDA also independently estimated the proportional effects of the proposed rule. In that **simulation** , the mean fraction of baseline illnesses prevented was 19 percent, the median was 15 percent... who were hospitalized, about 5 percent would die. The case-fatality rate simulated by the **model** equaled the probability of hospitalization multiplied by the conditional probability of death given hospitalization. In...

... calculations involved two steps. In the first step FDA used the USDA SE risk assessment **model** to estimate the number of illnesses prevented. In the second step, FDA estimated the health...used 50 uncertainty iterations, then 50 simulations of 500 iterations each.

In the Monte Carlo **simulation** , the computer repeatedly calculated health benefits based on the following formula:

total health benefits = (number...
... total health benefits once, based on single estimates for each value in the formula, the **simulation** calculated the health benefits over and over again. Each calculation (or iteration) used different values, with the values drawn from probability distributions. The probability distributions used in the **simulation** are shown in Table 8 of this document./13/

Note /13/ The agency selected distributions...

...were given. For discussions of the nature and use of these distributions in Monte Carlo **simulation** see Ref. 14.

Table 8.--Distributions Used to Estimate the Monetary Value of

Cases of...

...Discounted years of life lost 26.4 See text

per death of other victims

Each **simulation** calculated health benefits 1,000 times. FDA simulated the effects of the proposed rule, the... and the monetary value of preventing illnesses were randomly selected and then fixed for the **simulation** illustrated in Figure 2 of this document.

-The problem with Figure 2 of this document...

...Establishments Covered

The labeling provision and the refrigeration provision will affect different parts of the **food** industry.

a. Labeling provision coverage. The labeling provision covers shell eggs sold in labeled cartons...

... as hospitals providing prepared eggs to patients). These retail establishments include grocery stores, restaurants, health **food** stores, convenience stores, other retail establishments, as well as such institutions as prisons, nursing homes... administrative cost per firm multiplied by the number of firms that manufacture egg cartons. The **Food** Serving and Packaging Institute supplied information on the number of carton manufacturers (Ref. 19). Table...Dun's Market Identifiers (Ref. 25)./17/ If a State had already adopted the 1997 **Food** Code as issued by FDA or a similar code that required refrigeration to the proposed...
... included in this column are grocery stores (SIC 5411), poultry stands (SIC 5144), fruit and **vegetable** markets (SIC 5431), and dairy products stores (SIC 5451). Column D shows the number of...with insufficient cooling capacity can adversely affect the safety, quality, and shelf life of the **food** products, some establishments would be forced to purchase new

refrigerators or components.

All commercial refrigerators...equipment costs and some large firms could have small equipment costs.

Note /20/ In the **simulation** used to estimate total equipment costs, the distributions of small and large equipment costs were...

...and the probability that costs were large was 0.2. The full distribution for the **simulation** was: Discrete ((Beta Pert (0,700,1000), Beta-Pert (1000,4000,6000)), (0.8, 0.2)).

FDA estimated total equipment costs with a Monte Carlo **simulation** of 1,000 calculations (or iterations). Each calculation consisted of an estimate of the number... would be willing to pay more to continue to be able to eat the unsafe **food** , supposing it could be made safe. The extra willingness to pay is the measure of...

... practices when consumers are unable to purchase or prepare a safe version of the preferred **food** .

The agency calculated the cost of changing consumer practices with the following formula:
CS = E...

...The estimated number of eggs consumed was 46.8 billion. Based on results of the **Food** Consumption and Preparation Survey, the USDA SE risk assessment used a distribution with a most...

... minimum was 27 percent and the maximum was 46 percent. The distribution used in the **simulation** was Beta-Pert (0.27, 0.33, 0.46).

Note /23/ FDA used a Beta...

... distribution (50,959) was based on survey results for the USDA safe handling label for **meat** (Ref. 5). FDA used the same survey to estimate the benefits of the proposed safe handling label.
Note /24/ In the **simulation** , the value of an undercooked egg was characterized as a uniform distribution: Uniform ($0.001...

... the calculation, the agency estimated the costs of changing consumer practices with a Monte Carlo **simulation** . Table 20 of this document shows the results of the 1,000 calculations of the...

... benefits of this proposed rule to be about $300 million for the CDC surveillance baseline **model** and about $700 million for the USDA SE risk assessment baseline **model** . The estimated median costs to refrigerate shell eggs at 7.2 deg. C (45 deg...proposed rule would affect many small entities, including egg processors, grocery stores, restaurants, and other **food** service establishments. Of the 669 egg processors registered with the USDA, FDA has not been...

...code 5411) to be small if annual gross revenue is less than $20 million. Other **food** stores (SIC codes 5431, 5451, and 5499), which include fruit and **vegetable** markets, dairy product stores, and miscellaneous **food** stores, are small if annual sales are less than $5 million. Restaurants are small if...

...C (45 deg. F) is approximately 44,400, which includes 10,700 grocery and other **food** stores, 24,000 restaurants, and 9,700 institutions (see Table 15 of this document).
FDA...

...category. According to SBA size standards for small entities, 71 percent of grocery and other **food** stores and 54 percent of restaurants are small. Institutions are more complicated because they cut...Enteritidis Risk Assessment: Shell Eggs and Egg Products, Washington, DC: United States Department of Agriculture, **Food** Safety and Inspection Service, June 12,

1998.

3. Centers for Disease Control and Prevention (CDC...

... and F. J. Angulo, "Surveillance for Foodborne Disease Outbreaks--United Sates, 1988-1992," Journal of **Food** Protection, vol. 60, pp. 1265-1286, 1997.

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... and K. D. Fisher, "Estimating the Value of Consumers' Loss from Foods Violating the Federal **Food** , Drug, and Cosmetic Act," Research Triangle Report to the Center for **Food** Safety and Applied Nutrition, U.S. **Food** and Drug Administration, September 1988.

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...Arthritis, Federal Register 63, May 1, 1998.

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15. Kaplan, R. M., J. P. Anderson, and T. G...

...McAnally Enterprises, and Peter Vardon, FDA, January 21, 1998.
19. Letter from Richard B. Norment, **Food** Serving and Packaging Institute, to Peter Vardon, FDA, February 23, 1998.

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30. Putnam, J. Jones, and J. E. Allshouse, **Food** Consumption, Prices, and Expenditures, 1970-1995. Washington, DC: U.S. Department of Agriculture, Economic Research...

... Palumbo, and I. Walls, "Relationship Between Foodborne Bacterial Pathogens and the Reactive Arthritides," Journal of **Food** Safety, vol. 13, 1993.

32. Granfors, K., S. Jalkanen, A. A. Lindberg, O. Maki-Ikola...

...4 p.m., Monday through Friday.

Dated: June 10, 1999.
Jane E. Henney
Commissioner of **Food** and Drugs.

Donna E. Shalala,
Secretary of Health and Human Services.

(FR Doc. 99-17121...
19990706

17/K/28 (Item 2 from file: 180)
DIALOG(R)File 180:Federal Register

DIALOG Accession Number: 02496732 Supplier Number: 990700408
Food **Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution**
Volume: 64 Issue: 128 Page: 36492
CITATION NUMBER: 64 FR 36492
Date: TUESDAY, JULY 6, 1999

Food **Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held...**

...AGENCY: **Food** and Drug Administration...

...Center for **Food** Safety and Applied Nutrition

SUMMARY: The **Food** and Drug Administration (FDA) is proposing to require safe handling statements on labels of shell...

... that have not been treated to destroy this pathogen. These actions complement regulations of the **Food** Safety and Inspection Service (FSIS) that require that shell eggs be stored and transported at...

TEXT:
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
21 CFR Parts 16, 101, and 115
(Docket Nos. 98N-1230, 96P-0418, and 97P-0197)
RIN 0910-AB30
Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution
AGENCY: **Food** and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The **Food** and Drug Administration (FDA) is proposing to require safe handling statements on labels of shell...

... that have not been treated to destroy this pathogen. These actions complement regulations of the **Food** Safety and Inspection Service (FSIS) that require that shell eggs be stored and transported at...

...based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), **Food** and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of this proposed...

...at "http://www.fda.gov/cfsan".

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for **Food** Safety and Applied Nutrition (HFS-158), **Food** and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

SUPPLEMENTARY INFORMATION:
Table of Contents

... digestive tracts of animals, especially birds and reptiles. Human illnesses are usually associated with ingesting **food** or drink

contaminated with Salmonella, although infection may also occur person to person by the fecal- oral route...

... and vomiting. Symptoms of salmonellosis usually begin within 6 to 72 hours after consuming a **contaminated food** or liquid and last for 4 to 7 days. Most healthy people recover without antibiotic...In 1997, there were 44 reported outbreaks (Ref. 10). Many SE outbreaks were attributed to **food** served in commercial establishments, such as restaurants and other commercial **food** service establishments, hospitals, nursing homes, schools, prisons, private gatherings, and ships, with the implicated **food** containing undercooked eggs (Ref. 11). Although most deaths linked to reported SE-related outbreaks in...

... the predominant source of SE-related cases of salmonellosis in the United States where a **food** vehicle is identified (Ref. 13). From 1985 to 1993, consumption of eggs was associated with 83 percent of SE-related outbreaks where a **food** vehicle was identified (Ref. 14). Recent data indicate that egg-associated SE outbreaks still represent...

... outbreaks minus the number of outbreaks where the vehicle is unknown or where the implicated **food** is one other than eggs, i.e., chicken or turkey.

The Foodborne Diseases Active Surveillance...

... also be explained by a decline in the presence of Salmonella isolated from poultry and **meat** products because of recently implemented **HACCP** programs, or by some combination of egg quality assurance and **meat** /poultry **HACCP** program. In any event, FDA believes that the incidence of SE is still too high...

... contact clinical laboratories weekly or monthly to obtain data on numbers of cases.

B. Salmonella **Contamination** of Eggs
-Having evolved to protect the developing chick embryo, an egg provides a uniquely inhospitable environment for Salmonella and other bacterial **contaminants** . An egg's natural defenses are both mechanical and chemical. Mechanically, there are four barriers...reach the nutrient rich yolk, the microorganisms may then increase in number.

-Until recently, Salmonella **contamination** of shell eggs was thought most likely to be by trans-shell penetration of bacteria present in the egg's environment. The surface of an egg can become **contaminated** with any microorganism that is excreted by the laying flocks. In addition, contact with nesting...

...shipping and storage containers, human beings and other creatures may be a source of shell **contamination** . The likelihood of trans-shell penetration increases with the length of time that the eggs are in contact with **contaminating** materials.

-While environmental **contamination** is still a route for Salmonella **contamination** , it has recently been found that an egg's contents can become **contaminated** with SE before the egg is laid. Though the mechanism is still not well understood, SE will infect the ovaries and oviducts of some egg laying hens, permitting "transovarian" **contamination** of the interior of the egg while the egg is still inside the hen (Refs. 15 and-16). The site of **contamination** is usually the albumin.

-It is believed that only a small number of hens in...
...people to the risk of illness (Ref. 8).
FDA believes that it is this transovarian **contamination** that is responsible for the increased number of SE-related salmonellosis cases described in section...

... can be very low. For example, in a 1994 outbreak attributed to consumption of SE- **contaminated** ice cream, the highest level of **contamination** found in the implicated ice cream was only six

microorganisms per half-cup (65 gram...

... infective dose per serving was 25 microorganisms (Ref. 20). These reports indicate that low level **contamination** of foods with SE, and thus, low doses, can lead to illness. It is generally believed that SE-**contaminated** eggs initially contain only a few microorganisms (less than 20 microorganisms (Ref. 21)). Thus, the small number of microorganisms that initially may **contaminate** the egg may be sufficient to cause illness.

D. Inappropriate Handling of Eggs by Consumers and Other **Food** Preparers

-SE outbreak investigations show that outbreaks commonly occur when foods prepared with SE- **contaminated** eggs are not appropriately handled by consumers or other **food** preparers. Common practices inappropriate for foods containing SE- **contaminated** eggs include temperature abuse (i.e., failing to keep the eggs and foods prepared with...

...refrigerated) and inadequate cooking.

Pooling eggs to prepare a large volume of an egg-containing **food** that is subsequently temperature abused or inadequately cooked can cause illness in large numbers of people if any of the eggs were initially **contaminated** with SE.

-Temperature abuse gives SE the opportunity to multiply, thereby increasing the number of...

... up eggs) also allows ingestion of viable microorganisms if any of the eggs were initially **contaminated** . Incomplete cooking of eggs was associated with an SE outbreak in Tennessee, where the consumption of Hollandaise sauce served in a restaurant was linked to SE illnesses. Review of the **food** handling practices showed that the sauce had been prepared from eggs that were pooled, incompletely...19 percent of occasions when raw egg-containing products were consumed.

-The 1996 to 1997 **Food** Consumption and Preparation Diary Survey (Ref. 24) showed that 27 percent of all egg dishes...

...measures to eliminate viable SE in shell eggs, either through preventing transovarian and trans-shell **contamination** or through processing to destroy viable SE in shell eggs, with distribution safeguards to prevent...

... the 1998 ANPRM") that requests comments on farm-to-table actions that will decrease the **food** safety risks associated with shell eggs.

As mentioned previously, although fresh shell eggs provide a...R. K. Gast and C. W. Beard (Ref. 28) also found that infected hens can **produce** eggs with SE **contaminated** contents. Their study indicates that transovarian infection followed by limited room temperature storage (25 deg. C (77 deg. F)) resulted in **contamination** of the yolk membrane or albumin, or both, but not the contents of the yolk...

... SE during storage. These changes have the effect of bringing the yolk closer to the **contaminated** shell membranes when the egg is incubated in a position with the air cell uppermost. These investigators found that gross **contamination** of the albumin with SE was inhibited when the eggs were stored at 4 deg...

... less greatly extends the time that an egg can maintain its defenses against movement of **contaminating** bacteria such as Salmonella to the nutrient rich yolk, and, therefore, substantially reduces the likelihood...

... may be present, another measure a consumer may take to reduce the likelihood of consuming **contaminated** eggs is to thoroughly cook eggs. CDC reports that thorough cooking normally kills Salmonella that...

... boiled eggs, and sunny- side up eggs) can still contain viable Salmonella microorganisms. FDA's **Food** Code (a **model** code ...is published by FDA and intended for adoption by States and local authorities for governing **food** retail and **food** service establishments) requires that raw eggs that are broken and prepared in response to a...

...at 68 deg. C (155 deg. F) (Ref. 33).

G. Current Efforts

FDA and the **Food** Safety and Inspection Service (FSIS) of the USDA share Federal authority to regulate eggs for safety. FDA has jurisdiction over the safety of foods (except **meat** and poultry) generally, including shell eggs, under section 201 of the Federal **Food** , Drug, and Cosmetic Act (the act) (21 U.S.C. 321, et seq.) and under...

... Service, FSIS, AMS, and FDA all provide educational material on egg production methods that enhance **food** safety. FDA and FSIS work with States to encourage uniformity among state laws in retail and **food** service establishments through adoption of the **Food** Code. In addition, FDA, which has responsibility for investigating reports of SE outbreaks from foods...

... and efficient procedures for monitoring SE and effective and efficient ways to prevent SE from **contaminating** eggs. The findings from the pilot program were incorporated into the Pennsylvania Egg Quality Assurance...

...associated with shell eggs.

For example, in 1990, FDA reclassified eggs as a "potentially hazardous **food** " in the **Food** Code. The 1999 **Food** Code stipulates that potentially hazardous foods, including eggs, be maintained at 5 deg. C (41 ...

... with eggs and the fact that not all States have adopted this aspect of the **Food** Code, FDA tentatively concludes that stronger measures are necessary regarding handling of shell eggs.

On...

... for discussion on temperature control interventions and verification techniques in the transportation and storage of **meat** , poultry, seafood, and eggs and egg products. FSIS and FDA also published a joint ANPRM... Federal Register an ANPRM seeking to identify farm-to-table actions that will decrease the **food** safety risks associated with shell eggs. Information gathered from the foregoing measures will be considered...

... increased. CSPI further stated that consumers have no way of knowing that an egg is **contaminated** because eggs that are **contaminated** with SE have a normal appearance. The petition, suggested the following label statement: "Caution: Eggs...

...to this proposed rule, e.g., implementation of national standards for QA programs, implementation of **HACCP** , transportation of shell eggs, sell-by and expiration dates for shell eggs, housing and forced molting of chickens, repacking of eggs, and exportation of SE- **contaminated** into other countries. FDA will not address those comments in this proposed rule. There were...or processing any egg products, or otherwise using any eggs in the preparation of human **food** . FSIS defines an ultimate consumer as any household consumer, restaurant, institution, or other party who...
...S.C. 264(a))).

Salmonellosis is a communicable disease that can be caused by SE- **contaminated** eggs. Temperature abuse can lead to the multiplication of SE in shell eggs, and thereby...

... regional, it involves significant shipment of eggs from State to State. Moreover, shipment of SE- **contaminated** eggs from one State to another has contributed to the geographical spread of disease outbreaks...

... In addition, the agency tentatively concludes that the spread of salmonellosis among States from SE- **contaminated** eggs cannot be fully controlled without extending the refrigeration requirement to sales within one State. FDA believes that consumers who shop across State borders may purchase SE- **contaminated** shell eggs from one State and carry the eggs across State lines.

Thus, FDA is...

... processed, and sold in one State, the regulations will not prevent the introduction of SE **contaminated** eggs into other States and, thus, will not prevent the introduction of salmonellosis from one State to another.
The agency also notes that in the normal course of business, many **food** service establishments, e.g., restaurants, serve out-of-State customers, e.g., truck drivers, tourists...

... is concerned that if these out-of-State consumers become ill with salmonellosis from SE- **contaminated** eggs purchased through intrastate commerce, the disease could spread from one State to another. For...

...342(a)(4) and 371(a)).
Under section 402(a)(4) of the act, a **food** is adulterated if it is prepared, packed, or held in insanitary conditions whereby it may have been **contaminated** with filth or may have been rendered injurious to health. Under section 701(a) of...

... authorized to issue regulations for efficient enforcement of the act. Thus, a regulation that prohibits **food** from being held under insanitary conditions ... arena in a number of ways. First and foremost, FDA participates in the Conference on **Food** Protection which is the cooperative body responsible for making recommendations to FDA concerning the **Food** Code.
FDA also publishes the **Food** Code. In addition, FDA interacts with State and local regulatory agencies in a number of...
... Division of Federal-State Relations serves as the focal point for providing cohesive and uniform **food** policies to State associations and cooperating State and local officials. Retail **food** specialists work with State and local retail **food** regulatory agencies to assist them, when the Code has been adopted, in implementing the **Food** Code and to ensure through standardization of local and State health officials that the **Food** Code criteria are uniformly applied. Retail **food** specialists are located in FDA regional offices. Some districts may have partnership agreements with States...

... enforcement activities, and empowering cooperating organizations. This may also include assisting with implementation of retail **food** programs. FDA has structured the proposed regulation to take into account the traditional sharing of responsibilities of **food** safety at retail, augmented by a clear quantitative Federal standard for temperature control.

Under the...

... local governments as an important tool for public health officials. Previously, in the area of **food** safety, FDA has used those portions of the PHS Act (e.g., sections 310 and...
...242n and 243)) that focus on Federal assistance to the States.
Indeed, the Conference on **Food** Protection and the **Model Food** Code are a result of Federal/State/Local cooperation and Federal assistance to the States...

... allows the States, if certain conditions are met, to bring an action to enforce various **food** labeling provisions in the act. See 21 U.S.C. 337; 21 CFR 100.2...

... option will allow for the most effective and efficient use of Federal, State, and local **food** safety resources because it recognizes that States and localities, more than FDA, currently do this...

...requirements.

FDA recognizes that some of these approaches are new approaches to the enforcement of **food** safety regulations, and accordingly is soliciting, and will carefully review, comments on this aspect of this proposed regulation.
FDA is particularly interested in comments on how State, local, and Federal **food** safety authorities can best interface to ensure effective and efficient implementation and enforcement of **food** safety ...to ensure

the safety of shell eggs. As noted as follows in this section, the **Food** Code recommends that potentially hazardous foods be maintained at a temperature of 5 deg. C...

... The majority of comments to the 1998 ANPRM supported refrigeration of shell eggs throughout the **distribution chain** from packer to consumer. Most of these comments supported a requirement for an ambient temperature ...

... does not intend that this proposed regulation would, when finalized, preempt the requirements of the **Food** Code or other State or local requirements that require a lower temperature. The proposed regulation...

...shell eggs addresses growth of SE in shell eggs, whereas the temperature required by the **Food** Code addresses all pathogens that may be present in different types of potentially hazardous foods. Thus, in addressing holding temperatures for potentially hazardous foods generally, the **Food** Code requires a temperature for retail storage that will prevent or slow the growth of...retail and the refrigeration temperature of 5 deg. C (41 deg. F), recommended in the **Food** Code.

Because failure to refrigerate shell eggs would provide conditions for SE to multiply, the...

... have been present in the egg (e.g., Salmonella in the egg due to transovarian **contamination**). FDA is proposing in Sec. 115.50(c) that these eggs be exempt from the...

... requirement. However, such pasteurization would not prohibit the in-shell pasteurized egg from subsequently becoming **contaminated** with harmful microorganisms, if the egg were to come in contact with Salmonella or other...

... 38). Because this proposed regulation addresses the control of SE in shell eggs that are **contaminated** by transovarian transmission, the agency considers pasteurization an effective means to kill SE that may...

... when it is laid. Thus, the scope of this proposed regulation does not extend to **contamination** of eggs other than by transovarian transmission. FDA expects that manufacturers of this premium product...

... to destroy Salmonella are still considered to be potentially hazardous foods under provisions in the **Food** Code in part because they are raw eggs that are capable of supporting the growth...
... are considered potentially hazardous foods, State and local regulations established under the recommendations in the **Food** Code may have specific refrigeration requirements for these eggs in retail establishments that this regulation...

... this document, the agency tentatively concludes that the spread of salmonellosis among States from SE- **contaminated** eggs cannot be fully controlled without extending the refrigeration requirement to all eggs. Accordingly, FDA...

... in accordance with the EPIA because FDA tentatively concludes that it may be possible to **produce** safe egg products from shell eggs that have been held in violation of the regulation...I.D of this document, data from SE outbreaks show that outbreaks commonly occur when **contaminated** eggs are mishandled by consumers or other **food** preparers. Furthermore, consumption data establish that some consumers eat raw or undercooked eggs.

The CSPI...

... will be difficult for the industry to rapidly design and implement a program that will **produce** Salmonella-free eggs. However, as discussed in section I.F of this document, in the...
... outbreaks occur because of improper handling of eggs, e.g., pooling and incomplete cooking by **food** preparers. Most comments to the 1998 ANPRM that addressed labeling supported labeling cartons of eggs...

...included instructions on proper cooking of eggs.

The agency is concerned that unless consumers and **food** preparers are advised about both the risks presented by eggs **contaminated** with SE and the ways they can reduce these risks, consumers, particularly those at greatest...

...the PHS Act.
FDA's legal authority under the act to require label statements on **food** products derives from sections 201(n), 403(a)(1), and 701(a) of the act...

... Act that relate to communicable disease. Under section 403(a)(1) of the act, a **food** is misbranded if its labeling is false or misleading in any particular. Section 201(n...

...at the point of purchase.

However, the consequences that may result from consumption of SE-**contaminated** eggs may be reduced or eliminated by proper handling techniques that first limit the number...

... than avoidance of shell eggs, to reduce the risk of illness from consumption of SE- **contaminated** shell eggs. In light of this, the agency tentatively concludes that information on safe handling...this document, the agency believes that consumers who shop across State borders may purchase SE- **contaminated** shell eggs from one State and carry them across State lines. Therefore, without the inclusion...

...Failure to comply with the requirements of proposed Sec. 101.17(h) would render the **food** misbranded under section 403(a)(1) of the act and would violate regulations issued under...

...or repacked at a site other than originally processed or are shipped for use in **food** service establishments such as schools, hospitals, and restaurants also serves to inform repackers and **food** preparers of the safe handling procedures. However, FDA tentatively concludes that the same goal of conveying the safe handling labeling to repackers and **food** preparers could also be accomplished by customary trade practices. For example, the safe handling statement...
... labeled at a site other than where originally processed or are sold for use in **food** service establishments may be provided on cartons or in labeling, e.g., invoices or bills...

... predominance of SE in foodborne outbreaks, that consumers may not know that there is a **food** safety hazard associated with shell eggs. Consumption data indicating that some consumers eat raw or...

... but may not realize that they are particularly at risk for serious illness from a **food** long recognized to be a safe and inexpensive source of good nutrition. These people, especially...

...egg consumption. However, as previously discussed, the consequences that may result from consumption of SE- **contaminated** eggs may be reduced or eliminated by proper handling techniques. Failure to make clear that...

... that consumers can take to reduce or eliminate the risk associated with consumption of SE- **contaminated** eggs should be an essential element of the label statement. Because temperature has been reported... Ref. 25). Moreover, as a result of the safe handling instructions that appear on raw **meat** and poultry under rulemaking conducted by FSIS (59 FR 14528, March 28, 1994), consumers are...
... the safety of the eggs that they were purchasing. They were aware that the main **food** safety hazard posed by eggs was Salmonella **contamination** . Most of the participants kept their eggs refrigerated. However, many of them reported that they...

... protect themselves. In addition, a prescriptive label statement is consistent with label statements for other **food** products.

FDA believes that a regulation requiring a label statement on cartons of shell eggs...adequately inform consumers of measures that they can take to ensure the safety of the **food** . The agency tentatively concluded that the cooking instructions in the safe handling statement, i.e...

... other foods that contain eggs, the safe handling statement must convey to consumers that the **food** should be cooked thoroughly. Focus group research showed that although many consumers are aware that...

... infectious or toxigenic microorganisms that may be present. Growth of these microorganisms would render the **food** unsafe (62 FR 8248). ...for shell eggs, the agency encourages use of illustrations similar to those used on raw **meat** and poultry on the cartons of shell eggs. While the agency did not specifically test...
... with the consumer focus groups, the agency believes that, because graphic illustrations have been on **meat** and poultry product labels for some time, consumers have become familiar with these kinds of...of use. Two comments to the 1998 ANPRM requested that FDA provide flexibility in any **food** labeling statement, e.g., placement of the statement could occur on the inside of the...4) refrigeration at 5 deg. C (41 deg. F), (5) Hazard Analysis Critical Control Point (**HACCP**) for shell eggs, (6) in-shell pasteurization, (7) longer compliance periods, and (8) limited retail...

... effect on SE in shell eggs, but would increase costs substantially. FDA believes that a **HACCP** -like program (option 5) is currently not feasible. However, FDA is evaluating whether in the future, a **HACCP** -like program including possibly in-shell pasteurization, may be necessary to further ensure the safety...

...7.2 deg. C (45 deg. F) come from reducing SE-related illness. The basic **model** for estimating benefits is: "marginal health benefits = baseline risk (number of SE illnesses related to...

... Salmonella surveillance data for another estimate of the baseline. FDA also used the risk assessment **model** to estimate the expected reduction in illnesses attributed to the proposed rule. The design of the USDA SE risk assessment **model** allowed FDA to estimate the number of illnesses prevented by comparing the baseline number of...

...administrative compliance, inventory disposal, and label redesign costs. FDA calculated labeling costs with the following **model** : "labeling cost = ($ administrative costs per firm x number of affected firms) + ($ value of cartons manufactured...

...would require new equipment by assuming that no establishments in States that had adopted the **Food** Code and an uncertain fraction--with one-third the most likely value--of establishments in States that had not adopted the **Food** Code would require new equipment. FDA used industry sources to obtain estimates of the range...

... entities, including egg processors, grocery stores and other stores including roadside stands, restaurants and other **food** service establishments.
FDA has not been able to determine how many of the 669 egg...code 5411) to be small if annual gross revenue is less than $20 million. Other **food** stores (SIC codes 5431, 5451, and 5499), which include fruit and **vegetable** markets, dairy product stores, and miscellaneous **food** stores, are small if annual sales are less than $5 million. Restaurants are small if...

...C (45 deg. F) is approximately 44,400, which includes 10,700 grocery and other **food** stores, 24,000 restaurants, and 9,700 institutions (see the PRIA/IRFA document elsewhere in...

...category. According to SBA size standards for small entities, 71 percent of grocery and other **food** stores and 54 percent of restaurants are small. Institutions are more complicated, because they cut... Conference on Antimicrobial Agents and Chemotherapy.

3. Tauxe, R., "Salmonella: A Postmodern Pathogen," Journal of **Food** Protection, 54:563-568, 1991.

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20. Vought, K. J. and S. R. Tatini, "Salmonella enteritidis **Contamination** of Ice Cream Associated with a 1994 Multistate Outbreak," Journal of **Food** Protection, 61:5-10, 1998.

21. Humphrey, T. J., A. Whitehead, A. H. L. Gawler, A. Henley, and B. Rowe, "Numbers of Salmonella enteritidis in the Contents of Naturally **Contaminated** Hens' Eggs," Epidemiology and Infection, 106:489-496, 1991.

22. Klontz, K. C., B. Timbo, S. Fein, and A. Levy, "Prevalence of Selected **Food** Consumption and Preparation Behaviors Associated With Increased Risks of **Food** -borne Disease," Journal of **Food** Protection, 58(8):927-930, 1995.

23. Market Research Corp. of America, Consumption of Raw...

... J., R. A. Morales, and K. Ralston, "Raw and Undercooked Eggs: A Danger of Salmonellosis," **Food** Review, 20:27-32, 1997.

25. FDA Memorandum, Alan S. Levy, Ph.D. to Kenneth...

...735-742, 1989.

28. Gast, R. K. and C. W. Beard, "Production of Salmonella enteritidis-- **Contaminated** Eggs by Experimentally Infected Hens," Avian Diseases, 34:438- 446, 1990.

29. Clay, C. E. and R. G. Board, "Growth of Salmonella enteritidis in Artificially **Contaminated** Hens' Shell Eggs," Epidemiology and Infection, 106:271-281, 1991.

30. Humphrey, T. J., "Growth...

... of Salmonella enteritidis in Yolk of Shell Eggs from Normal and Seropositive Hens," Journal of **Food** Protection, 53:1033-1036, 1990.

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32. Centers for Disease Control and Prevention, "Update: Salmonella enteritidis...

...Morbidity and Mortality Weekly Report, 36:204-205, 1987.

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34. White, P. L...

... Environmental Survey by Manure Drag Sampling for Salmonella enteritidis in Chicken Layer Houses," Journal of **Food** Protection, 60:1189-1193, 1997.

35. Salmonella Enteritidis Review Team Report, January 18, 1997.

36...

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39. Macro International, Inc., Focus Group Testing of Safe Handling...

...Shell Eggs, April 1998.

39A. Macro International, Inc., Focus Group To Assess Consumer Reactions to **Food** Safety Issues (U.S. **Food** and Drug Administration), Certified Tape Transcripts.

40. FDA memorandum, Peter Vardon to the Record, October...
...CFR Part 16
Administrative practice and procedure.

21 CFR Part 101
Administrative practice and procedure, **Food** labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 115
Administrative practice and procedure, Eggs, Refrigeration.

Therefore, under the Federal **Food** , Drug, and Cosmetic Act and the Public Health Services Act, and under the authority delegated to the Commissioner of **Food** and Drugs, it is proposed that 21 CFR chapter I be amended as follows:
PART 16--REGULATORY HEARING BEFORE THE **FOOD** AND DRUG ADMINISTRATION
1. The authority citation for 21 CFR part 16 continues to read...S.C. 264), Secs. 101.17(h) and 115.50 of this chapter.

* * * * *
PART 101-- **FOOD** LABELING
3. The authority citation for 21 CFR part 101 is revised to read as...
...the section heading and by adding paragraph (h) to read as follows:
Sec. 101.17 **Food** labeling warning, notice, and safe handling statements.

* * * * *
(h) Shell eggs. (1) The label of shell...

...labeled at a site other than where originally processed, or are sold for use in **food** service establishments, may be provided on cartons or in labeling, e.g., invoices or bills...

...satisfy due process.

(8) This paragraph (h) is established under authority of both the Federal **Food** , Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the **food** misbranding provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U...

... a written order that such eggs be diverted (from direct consumer sale, e.g., to **food** service) under the supervision of an officer or employee of the issuing entity, for processing...is served may either comply with the order or appeal the order to the regional **food** and drug director.
-(A) Appeal of a detention order. Any appeal shall be submitted in...

... at any time after a request for a hearing has been submitted, if the regional **food** and drug director or his or her designee determines that no genuine and substantial issue...

... material submitted in connection with the hearing or from matters officially noticed.
If the regional **food** and drug director determines that a hearing is not justified, written notice of the determination...

... in person, with or without counsel. The informal hearing shall be conducted by the regional **food** and drug director or his designee, and a written summary of the proceedings shall be prepared by the regional **food** and drug director.

(1) The regional **food** and drug director may direct that the hearing be conducted in any suitable manner permitted by law and this section. The regional **food** and drug director has the power to take such actions and

make such rulings as...

...be furnished to FDA. Any transcript of the hearing will be included with the regional **food** and drug director's report of the hearing.

(5) The regional **food** and drug director shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the regional **food** and drug director may give the parties the opportunity to review and comment on the report of the hearing.

(6) The regional **food** and drug director shall include ...If the appellant appeals the detention order but does not request a hearing, the regional **food** and drug director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(E) Regional **Food** and Drug Director decision. If, based on the evidence presented at the hearing or by the appellant in a written appeal, the regional **food** and drug director finds that the shell eggs were held in violation of this section...

... or under the supervision of an officer or employee of the FDA; otherwise, the regional **food** and drug director shall issue a written notice that the prior order is withdrawn. If the regional **food** and drug director affirms the order he shall order that the relabeling, diversion, or destruction...

... within 10-working days from the date of the issuance of his decision. The regional **food** and drug director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the regional **food** and drug director shall constitute final agency action, reviewable in the courts.

(F) No appeal...

...destroy them within 10-working days, or if the demand is affirmed by the regional **food** and drug director after an appeal and the person in possession of such eggs fails...

... a "retail establishment" is an operation that stores, prepares, packages, serves, vends, or otherwise provides **food** for human consumption directly to consumers.

(b) Except as provided in paragraph (c) of this...

...procedures satisfy due process. --
(f) This section is established under authority of both the Federal **Food**, Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the **food** adulteration provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U...director.

(iii) Approval of District Director. An order, before issuance, shall be approved by the **Food** and Drug Administration (FDA) District Director in whose district the shell eggs are located. If...

... is served may either comply with the order or appeal the order to the regional **food** and drug director in accordance with the following procedures:
(i) Appeal of a detention order...

... at any time after a request for a hearing has been submitted, if the regional **food** and drug director or his or her designee determines that no genuine and substantial issue...

... material submitted in connection with the hearing or from matters officially noticed.
If the regional **food** and drug director determines that a hearing is not justified, written notice of the determination...

... in person, with or without counsel. The informal hearing shall be conducted by the regional **food** and drug director or his designee, and a written summary of the proceedings shall be prepared by the regional **food** and drug director.

(A) The regional **food** and drug director may direct that the hearing be conducted in any suitable manner permitted by law and this section. The regional **food** and drug director has the power to take such actions and make such rulings as...be furnished to FDA. Any transcript of the hearing will be included with the regional **food** and drug director's report of the hearing.

(E) The regional **food** and drug director shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the regional **food** and drug director may give the parties the opportunity to review and comment on the report of the hearing.

(F) The regional **food** and drug director shall include as part of the report of the hearing a finding...

... If the appellant appeals the detention order but does not request a hearing, the regional **food** and drug director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(v) Regional **Food** and Drug Director decision. If, based on the evidence presented at the hearing or by the appellant in a written appeal, the regional **food** and drug director finds that the shell eggs were held in violation of this section...

... or under the supervision of an officer or employee of the FDA; otherwise, the regional **food** and drug director shall issue a written notice that the prior order is withdrawn. If the regional **food** and drug director affirms the order he shall order that the diversion or destruction be...

... within 10-working days from the date of the issuance of his decision. The regional **food** and drug director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the regional **food** and drug director shall constitute final agency action, reviewable in the courts.

(vi) No appeal...
...destroy them within 10-working days, or if the demand is affirmed by the regional **food** and drug director after an appeal and the person in possession of such eggs fails...

LEGAL PUBLICATIONS:
...Pub. Law 90-201 SEC. 16 -- Federal **Meat** Inspection Act of 1967...

... Pub. Law 59-242 SEC. 409 -- Department of Agriculture Appropriations Act, 1908; Federal **Meat** Inspection Act of 1907...

...Pub. Law 75-717 SEC. 402 701 201 403 301 409 -- Federal **Food** , Drug and Cosmetic Act (Act of 6/25/38...

... Holding Company Act of 1958; Public Utility Holding Company Act, Amendment (8/28/58); Federal **Food** , Drug and Cosmetic Act, Amendment (8/28/58...

...Pub. Law 85-929 SEC. 4 -- Federal **Food** , Drug and Cosmetic Act, Amendment (9/6/58)
19990706

17/K/29 (Item 3 from file: 180)

DIALOG Accession Number: 02424249 Supplier Number: 970600867
HACCP -Based Meat and Poultry Inspection Concepts
Volume: 62 Issue: 111 Page: 31553
CITATION NUMBER: 62 FR 31553
Date: TUESDAY, JUNE 10, 1997

HACCP -Based Meat and Poultry Inspection Concepts

...AGENCY: **Food** Safety and Inspection Service...

...Office for **Food** Safety

SUMMARY: The **Food** Safety and Inspection Service (FSIS) must change how resources are allocated in order to improve regulation of the **meat** and poultry industries after implementation of the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/ **HACCP**)Systems final rule. Every aspect of traditional FSIS methods of inspection for slaughter and processing...

... change as long as the Agency can fulfill its responsibilities to ensure that the industries **produce** safe, wholesome, unadulterated and properly labeled **meat** and poultry products. The Agency is also considering adding methods to better ensure **food** safety and other consumer protections in distribution channels.
FSIS is seeking comments on the development of new inspection models for slaughter and processing in a **HACCP** environment. FSIS also invites the public to participate in the development of new inspection models...

TEXT:
DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

(Docket No. 96-008N)

HACCP -Based **Meat** and Poultry Inspection Concepts

AGENCY: **Food** Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The **Food** Safety and Inspection Service (FSIS) must change how resources are allocated in order to improve regulation of the **meat** and poultry industries after implementation of the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/ **HACCP**)Systems final rule. Every aspect of traditional FSIS methods of inspection for slaughter and processing...

... change as long as the Agency can fulfill its responsibilities to ensure that the industries **produce** safe, wholesome, unadulterated and properly labeled **meat** and poultry products. The Agency is also considering adding methods to better ensure **food** safety and other consumer protections in distribution channels.

FSIS is seeking comments on the development of new inspection models for slaughter and processing in a **HACCP** environment. FSIS also invites the public to participate in the development of new inspection models...

... sections. Section I (Introduction) explains the current status of the FSIS regulatory program and its **food** safety goals and strategy, and describes the Agency's consumer protection activities included in its...

... effort. Section II (Current Inspection System) explains the current program and identifies significant inconsistencies between **HACCP** and the current program. This section also summarizes external support for inspection reform.
Section III (**HACCP** -based Inspection Development Project) explains the project, describes inspection **model** development activities, announces a public process to assist in the development of new inspection models...

... Public Meeting) proposes material questions the Agency will address through the public process.

I. Introduction

Food Safety Goal

FSIS is committed to making fundamental improvements in the safety of America's **meat** and poultry supply in order to reduce the incidence of foodborne illness. In the preamble to the proposed rule "Pathogen Reduction; Hazard Analysis and Critical Control Points (PR/ **HACCP**) Systems" (60 FR 6774; February 3, 1995), FSIS stated its goal as follows: "* * * to reduce the risk of foodborne illness associated with the consumption of **meat** and poultry products to the maximum extent possible by ensuring that appropriate and feasible measures are taken at each step in the **food** production process where hazards can enter and where procedures and technologies exist or can be...

... An essential first step in achieving that goal was accomplished with promulgation of the PR/ **HACCP** Systems final rule (61 FR 38806; July 25, 1996).

The PR/ **HACCP** final rule mandates substantial change within every inspected **meat** and poultry establishment. The new regulations: (1) Require that each establishment develop, implement, and follow...

... to verify the adequacy of their process controls for the prevention and removal of fecal **contamination** and associated bacteria; (3) establish pathogen reduction performance standards for Salmonella that slaughter establishments and establishments producing raw ground products must meet; and (4) require that all **meat** and poultry establishments develop and implement a risk-based system of preventive controls known as **HACCP** to improve product safety.

In mandating these reforms, FSIS recognized that in-plant technological and procedural solutions could not address foodborne illness hazards occurring in **meat** and poultry products outside official establishments. These components of the goal could be achieved only through a more comprehensive **food** safety strategy that would bring about improvements in risk management at each step in the **meat** and poultry production chain. Efforts must extend from just before slaughter, through slaughter, processing, distribution, and retail sale or **food** service, to consumers.

FSIS' **Food** Safety Strategy

The **food** safety strategy FSIS outlined in its PR/ **HACCP** final rule included five major elements:
(1) Provision for systematic prevention or reduction of biological, chemical, and physical hazards through adoption by **meat** and poultry establishments of science-based process control systems.

(2) Targeted efforts to control and reduce harmful bacteria on raw **meat** and poultry products.

(3) Adoption of **food** safety performance standards that provide a catalyst for innovation to improve **food** safety and a measure of accountability for achieving acceptable **food** safety results.

(4) Removal of unnecessary regulatory obstacles to innovation.

(5) Efforts to address hazards that arise throughout the **food** safety continuum from farm to table.

FSIS also stressed, as a central theme of its...

... need to clarify and strengthen the responsibilities of establishments for maintaining effective sanitation, following sound **food** safety procedures, and achieving acceptable **food** safety results.

The PR/ **HACCP** final rule included regulatory provisions to implement **food** safety strategy components (1) Hazard prevention through **HACCP** and other production control systems, (2) reduction and control of bacterial pathogens and (3) adoption of **food** safety performance standards. Earlier, FSIS had published an Advance Notice of Proposed Rulemaking (ANPR) (60...

... review of all FSIS regulations to determine which will still be needed when the PR/ **HACCP** final rule becomes effective and which ought to be revised, streamlined or eliminated. That review...

... to consolidate and remove or modify existing requirements to make them performance standards.

The PR/ **HACCP** final rule did not address hazards arising at other points in the farm to table continuum: for instance, during the transportation, storage and retail, restaurant or **food** service sale of **meat** and poultry products. Yet each stage of production presents hazards of pathogen and other **contamination** and each provides opportunities for preventing or mitigating these hazards.
Those in control of each...

... table continuum must accept their share of the responsibility for identifying and preventing or reducing **food** safety hazards that are under their operational control.

FSIS's **food** safety mandate requires that the Agency address foodborne illness hazards within each segment of the **food** production chain and that it implement and encourage prevention strategies that improve the whole system.
FSIS remains committed to a farm to table **food** safety strategy based on these principles. Commenters on the PR/ **HACCP** proposed rule supported FSIS modernization of its regulatory program to include all segments of the **food** production and transportation industries.
The Agency also will be cooperating with animal producers, academia, the Animal and Plant Health Inspection Service, the **Food** and Drug Administration, the States, and other government agencies to develop and foster voluntary **food** safety measures which can be taken on the farm to decrease the public health hazards in animals presented for slaughter.

The post-processing transportation, storage, and retail restaurant or **food** - service sectors are also important links in the chain of responsibility for **food** safety. In these areas, FDA and State and local governments share authority and responsibility for oversight of **meat** and poultry products outside of official establishments. FSIS, FDA, and the State and local agencies...

... they are to reduce foodborne illness to the maximum extent possible, they must coordinate their **food** safety missions when addressing hazards that may arise in distribution and at retail. FSIS has...

... perishable foods and to recommend reasonable controls that might be employed by industry to ensure **food** safety. Using the **HACCP** system, the TAG conducted a hazard analysis of the two major areas of concern in...

...are perishable. The TAG concluded that a program to ensure more sanitary and temperature-controlled **food** transportation would benefit both the industry and consumers.

In conjunction with FDA, FSIS issued a...

... ideas related to in-distribution regulatory activities to be considered by FSIS and FDA regarding **meat** , poultry, eggs, seafood, dairy, and other potentially hazardous **food** products. A transcript of this conference is available from the FSIS hearing clerk.

Other Consumer Protection Activities

In addition to its **food** safety goal, FSIS also has other consumer protection responsibilities under the laws it administers that are the subject of many agency activities. These include ensuring that **meat** and poultry products are truthfully labeled and not economically adulterated with less valuable components such as water, and ensuring that consumers are protected from unwholesome **meat** and poultry products which, while not actually unsafe, might contain components which are undesirable.

Regulatory...

...FSIS regulatory program of the future will be designed first to meet the Agency's **food** safety goal and strategy, along with our consumer protection responsibilities. The Agency realizes it must have the participation of all stakeholders to achieve our **food** safety goal and other objectives. FSIS is therefore seeking public input on the design and development of its **HACCP** -based program. FSIS believes that there are at least three essential objectives that will form the basis of this modern **HACCP** - based program.

** First, FSIS must ensure that any new inspection models do not diminish the current **food** safety and consumer protection achievements that result from (1) carcass-by-carcass and bird-by...

... objective is to effectively and efficiently oversee, evaluate, and verify industry implementation of the PR/ **HACCP** final rule.
HACCP , combined with other production control systems and FSIS inspection oversight, are complementary and interrelated, but for any changes.

** The third regulatory objective is to ensure that **meat** and poultry products are handled and transported by allied industries under conditions which maintain their...

... FSIS intends to gather information about industry practices relative to handling, transport, and storage of **meat** and poultry products to determine whether businesses are effectively managing **food** safety risks and ensuring that other consumer protections remain intact.

Need for Resource Redeployment

FSIS will be unable to meet its **food** safety goal and other regulatory objectives unless it changes the way it deploys its resources...

... be allocated to new inplant functions associated with oversight, evaluation, and verification of the PR/ **HACCP** final rule implementation. Other redeployed resources could be assigned to in-distribution oversight.

II. The...

...present barriers to the efficient and effective allocation of resources.

FSIS now carries out its **meat** and poultry **food** safety responsibilities primarily through in-plant slaughter and processing inspection programs.
Under the current in...

... parts are presented for inspection with the intention of being prepared for use as human **food** . FSIS inspectors are required to determine which are wholesome, not adulterated, and capable of use as human **food** . FSIS

inspectors decide whether to pass, condemn, or allow salvage of carcasses or parts thereof...

... to public health risk. For instance, the current line inspection system required by regulation in **meat** and poultry slaughter establishments focuses substantial FSIS inspection resources on areas that do not present significant **food** safety risks. The carcass inspection procedures carried out by FSIS inspectors today were designed many...

...of defects as indicators of possible microbial risk. Measuring microbial hazards in the design of **HACCP** plans through testing for actual microbial levels and validation of control measures will occur during implementation of the PR/ **HACCP** final rule. Since new inspection models should reflect this focus on pathogen reduction and microbial...
...carcass defects that result in condemnation by FSIS slaughter inspectors today are aesthetic rather than **food** safety related, such as pigmentary conditions and tumors. Condemnation for **food** safety reasons is even lower, 0.4 percent of young chickens, 0.08 percent of...

... directly observe 1,000 young chickens to find four (4) that should be condemned for **food** safety concerns. Similarly 10,000 steers and heifers are observed to condemn eight (8) and...and crucial to the development of new inspection models. Certain diseases and conditions unrelated to **food** safety, but currently addressed in the regulations, may be more appropriately addressed by industry monitoring...

...1/

Septicemia/toxemia	Yes	23,684,719	0.30
Synovitis	No	489,101	0.01
Contamination	Yes	6,190,429	0.08
Manufacturing defects	No	20,984,146	0.28
Aesthetic...			

... as bruises, cadaver, over scalded, missing viscera, and plant rejects. Aesthetic conditions with no known **food** safety concern include leukosis, other tumors, and airsacculitis.

Table 2.--FY 1995 Condemnation Data for...

...that many condemnations are unrelated to public health risks, today FSIS still fully staffs every **meat** and poultry establishment slaughter line inspection station. Assigning top priority to slaughter line inspection activities...

... defects of public health concern directly affects the Agency's ability to staff other critical **food** safety inspection activities and may not be the best use of inspection resources. For example...

...new technology and improved production procedures.
Establishments should have the flexibility to implement the PR/ **HACCP** final rule and to make decisions about how they may best control **food** safety hazards and meet performance standards. Establishments should have the latitude to develop new production control methods to detect **food** safety and non- **food** safety related defects in carcasses and parts. Current slaughter inspection methods, particularly fixed inspector stations ...

... General Accounting Office, and by FSIS have established the need for fundamental change in the **meat** and poultry inspection program. Two elements have been commonly expressed: FSIS should revise and reform inspection to (1) Improve **food** safety through a reduction in foodborne illness caused by pathogenic bacteria on **meat** and poultry products and (2) make better use of its resources. Bacteria, including Salmonella, E. Coli 0157:H7, Campylobacter and Listeria Monocytogenes, are significant **food** safety hazards associated with **meat** and poultry products.
The **contamination** of **meat** and/or poultry with these bacteria is estimated to result annually in as many as...

... and shift to prevention-oriented inspection systems based on risk assessment. The 1985 NAS report, **Meat** and Poultry Inspection: The

Scientific Basis of the Nation's Program, recommended that FSIS focus on pathogenic organisms and require that all official establishments operate under a **HACCP** system for control of pathogens and other safety hazards. This report strongly encouraged "FSIS to move as vigorously as possible in the application of the **HACCP** concept to ...establishment operations, in all types of enterprises involved in the production, processing, and storage of **meat** and poultry products."

Two later NAS studies reinforced this recommendation. The 1987 NAS report Poultry...

... on Evaluation of USDA Streamlined Inspection System for Cattle (SIS-C) added that although "traditional **meat** inspection, relying on organoleptic examinations, can ensure satisfactory **meat** product quality, it is not fully effective in protecting the public against foodborne health hazards ...

... detectable with these techniques. The future will require new ways of preventing public exposure to **contaminants** , scientifically valid and believable methods of evaluating inspection technology, and implementation of appropriate portions of **HACCP** programs."

The General Accounting Office (GAO) has advocated similar improvements for **meat** and poultry inspection in its reports. (**Food** Safety: A Unified, Risk- Based **Food** Safety System Needed (1994); **Meat** Safety: Inspection System's Ability to Detect Harmful Bacteria Remains Limited (1994); **Food** Safety: Building a Scientific, Risk-Based **Meat** and Poultry Inspection System (1993); **Food** Safety and Quality--Uniform, Risk-Based Inspection System Needed to Ensure Safe **Food** Supply (1992).) The GAO has endorsed **HACCP** as a scientific, risk-based system that would permit redeployment of FSIS resources in a manner that will better protect the public from foodborne illness. The 1994 GAO report, **Meat** Safety: Inspection System's Ability to Detect Harmful Bacteria Remains Limited, stated the resource problem...

... system. Such a system would allow FSIS to target its resources toward the higher-risk **meat** and poultry products by increasing inspection of such products."

Another proponent of inspection reform has...

... on Microbiological Criteria for Foods (NACMCF), which prepared reports on the development and implementation of **HACCP** . NACMCF supported the use of risk analysis for allocation of resources to control **food** safety.

III. **HACCP** -Based Inspection Development Project

With this notice, FSIS is initiating the process of dialogue with...

... development of new inspection models to be tested in a series of trials in volunteer **meat** and poultry slaughter establishments and in distribution channels. This project is intended to **produce** a fully integrated system of regulatory oversight and controls that will permit FSIS to deploy...

...more effectively in-plant and between in-plant and in-distribution sites in accord with **food** safety and other consumer protection requirements.

Objectives for New Inspection Models

The development of new...

... track development is to test and refine the new inspection concepts in both commercially operating **meat** and poultry establishments and with in-distribution activities at several geographic sites. Throughout the development...

... papers presented at the meeting will be available in the FSIS Docket Clerk's Office, **Food** Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700.

Development Phase...

... they tend to be healthy and uniform; they also represent over ninety percent (90%) of **meat** and poultry slaughtered in the United States.

Slaughter and combination slaughter and processing plants participating as volunteers will be required to have **HACCP** and other production controls in place to ensure that all consumer protection goals of the...and type of slaughter lines, and a certification that all applicable elements of the PR/ **HACCP** final rule have been or will be fully implemented. FSIS will conduct an on-site...

... that products bearing the official inspection mark are not adulterated or misbranded, including verification of **HACCP** or S- SOP's. Such changes would provide FSIS with considerable data with which to...

... perform (1) carcass-by- carcass and bird-by-bird slaughter inspection oversight, (2) verification of **HACCP** and related production control systems, (3) verification of establishment S-SOP's and (4) sampling...

... by in- distribution oversight and tasks to determine the feasibility, efficiency, and effectiveness of performing **food** safety and other consumer protection tasks in distribution.

Completion

Upon completion of the development activities...
...and in-distribution models accepted for testing. The models should:
1. Emphasize industry responsibility for **food** safety and other consumer protection activities and government responsibility to verify that these objectives are...

...management.

3. Prioritize in-plant work to meet current inspection system objectives and verify that **HACCP** and other control systems and sanitation procedures are effective; provide appropriate priority to other consumer...

... regulatory work, including oversight of how industry manages health and safety hazards that occur after **meat** and poultry products leave a USDA-inspected establishment and verification that products in-distribution are...

... establishments to help the Agency properly allocate resources between oversight, evaluation and verification of PR/ **HACCP** final rule implementation and activities to accomplish other consumer protection objectives. The new in-plant...

...plant Inspection Models

A variation of the current inspection system has been identified as a **model** to be considered and discussed at the public meeting announced by this notice.

Under this in-plant **model** , the establishment would initiate **HACCP** and related control systems to distinguish acceptable from unacceptable carcasses and parts using current regulatory requirements for antemortem and postmortem disposition of carcasses and parts.

This **model** would provide establishments maximum flexibility to design and exercise more effective and more efficient production...

... not adulterated or misbranded. Consequently, establishment product flow plans crafted for compliance with the PR/ **HACCP** final rule for other production control purposes would not include fixed FSIS inspection stations.

FSIS the establishment that contribute to product safety and wholesomeness.

FSIS envisions this inspection **model** as having three main components that collectively would ensure equivalent performance to that level of **food** safety and other consumer protections provided by the current regulatory system.
Slaughter performance standards that...

... component is verification of the overall establishment program for producing acceptable product including verification of **HACCP** , other production control systems, and S-SOP's.

This preliminary in-plant inspection **model** envisioned by FSIS would require fewer inspectors assigned to slaughter plants, making inspectors currently assigned to slaughter line positions available for redeployment. This is consistent with **HACCP** principles and would reduce or eliminate distinctions between slaughter and processing inspection by allowing inspectors to rotate from post-mortem oversight positions to work such as **HACCP** verification, finished product standards testing, Performance Based Inspection System (PBIS) task performance, S-SOP verification and microbial sampling.

FSIS Verification Activities
Under the new in-plant inspection **model** , FSIS would not prescribe how industry must accomplish production control. Establishments would instead be provided...

... processes that address hazards and defects unique to their operations. FSIS would ensure that establishment **HACCP** and other control system plans for achieving regulatory standards are adequate and operating properly. Following...

...to the Performance-Based Inspection System, including those historically performed after slaughter during processing.

** Conduct **HACCP** record reviews to verify that the establishment is monitoring critical control points in accordance with their **HACCP** plan.

** Verify establishment disposition of rejected product.

** Conduct operational verification activities, such as assessing the establishment's execution of its **HACCP** plan.

** Take samples of product for microbiological, chemical and physical analysis to verify establishment compliance with its **HACCP** plan.

** Verify that the establishment is following its sanitation SOP.

The FSIS Veterinary Medical Officer...

...VMO expertise and responsibilities would include the following:
** Serve as the Inspector-in-Charge; supervise **food** inspectors.

** Evaluate the health of incoming animals through ante-mortem activities.

** Perform ante-mortem inspection...

...Distribution Concept

A new in-distribution inspection concept should provide for verifying industry management of **food** safety risks that arise after inspection.
Resource allocation issues require an integrated approach for both **food** safety and other consumer protection initiatives. Thus, the in-distribution **model** may also supplement in-plant oversight of product labeling, economic adulteration and wholesomeness requirements. Although...

...two activities.

At present, FSIS has no comprehensive rules governing the in-distribution handling of **meat** and poultry products. The Agency now exercises its jurisdiction over product outside inspected establishments to a limited degree. For example, FSIS has promulgated safe handling labels for raw **meat** and poultry products (9 CFR 317.2 (l) and (m), and 381.125(b)); in ...

... concerning transportation to and among inspected establishments and allied industries, such as renderers and pet **food** establishments, conducts scheduled and unscheduled reviews of warehouses and other in-distribution locations, verifies thethe statutes provide USDA authority to oversee **meat** and poultry products after they leave inspected establishments. The statutes provide that one may not "sell, transport, offer for sale or transportation, or receive for transportation" any **meat** or poultry product that is capable of use as human **food** and is "adulterated or misbranded at the time of such sale, transportation, offer for sale...

...d) and 458(a)(3)).

This authority would encompass the establishment of safety standards for **meat** and poultry products from the time they leave an inspected establishment to final sale or...

...whether performance standards and Good Manufacturing Practices could and whether they can be established for **meat** and poultry products to prevent growth of harmful bacteria and introduction of other potential hazards...

... with transportation of perishable foods and controls that might be employed by industry to ensure **food** safety. The TAG noted "that time, temperature, and sanitation are the three key elements of...

... of product temperature in transit, time in transit, and practices to reduce opportunities for cross **contamination** all represent control points for which the development of regulatory standards, good manufacturing practices, and...

... include allied industry members who volunteer to describe quality or safety problems they experience with **meat** and poultry received from their suppliers. These data will suggest points of concern within the **distribution chain** that FSIS may need to address in its inspection planning.
Another data collection effort could...

... certain products or product lots as they leave inspected establishments and track them through the **distribution chain** to detect and record changes caused by allied industry handling practices. The nationwide status of the **food** safety and other consumer protection aspects of **meat** and poultry products could be evaluated and profiles developed. Evaluation of changes in profiles over time would measure the effectiveness of in-distribution efforts to maintain **food** safety and product integrity. Status reports on **meat** and poultry products might be correlated with sentinel site surveillance data for foodborne disease to track the public health impact of farm to table **food** safety initiatives.

While time, temperature, and sanitation play a key role in controlling hazards to...

... foods in transportation, they are not the only factors that could be verified in the **distribution chain** . FSIS will also determine whether some adulteration and misbranding inspections presently conducted in- plant can be supplemented or perhaps performed entirely in-distribution. Many **meat** and poultry products are prepared by regulated establishments in consumer-ready packages. Samples could be...
... identified both available information and information gaps. Allied industries responsible for transportation and storage of **meat** and poultry have addressed product integrity issues for sometime. For example, cold storage facilities, warehouses...

...adequately known to FSIS.

FSIS identified several alternatives to ensure safe transportation and storage of **food** in its ANPR of November 22, 1996: Transportation and Storage Requirements for Potentially Hazardous Foods...

... alternatives include specific requirements, such as temperature standards, performance standards, record keeping to ensure that **food** safety controls are maintained, mandatory **HACCP** -type systems, voluntary guidelines, and combined approaches. These alternatives are summarized below.

1. Temperature Requirements...

... to and maintained at or below a specific temperature during transportation and storage from the **food** processing plant to the retail outlet, restaurant, or other establishment serving the consumer. If this approach is adopted, all potentially hazardous foods being transported to retail or **food** service establishments would have to be maintained at or below such a maximum temperature.

2...

... carriers of potentially hazardous foods that are shipped in bulk (foods which directly contact a **food** conveyance) to provide **food** shippers with records that identify the last three cargoes for any conveyance being offered to the **food** shipper for use in transporting the **food** and that disclose the data of the most recent cleaning of the conveyance.

3. Mandatory **HACCP** -Type Systems

Another approach would be to require that a **HACCP** system be established specifically with respect to the transportation and storage of potentially hazardous foods to prevent the **contamination** of these foods. Such requirements could be modeled on the regulations recently adopted by FSIS that apply to establishments processing **meat** and poultry.

Such **HACCP** -type systems could be ...The use of a temperature standard would allow processors to determine the acceptability of a **food** transport vehicle for the transport of certain bulk foods, i.e., those that pose a...

... 61 FR 59372), could serve as the basis for developing joint government-industry guidelines for **food** transportation and storage.

V. Public Meeting

Public participation in the development and implementation of the...

... that comments addressing the following questions will facilitate the public process.

** What are the priority **food** safety objectives that must be accomplished by FSIS' **meat** and poultry inspection system?
** What other significant consumer protections should the **meat** and poultry regulatory system provide?
** How should the agency prioritize **food** safety and other consumer protection objectives?
** How much emphasis should FSIS place on detection of aesthetic defects that are not related to **food** safety?
** A major objective of the S-SOP requirement in the PR/ **HACCP** regulation was to make establishments more accountable for performing all necessary sanitation functions before and...

... best coordinate with State and local authorities to minimize restaurant

and institutional outbreaks linked to **meat** and poultry products?
** How can FSIS verify allied industry management of **food** safety risks as **meat** and poultry products move from the establishment to consumers?
** What systems do establishments have in place for ensuring in-distribution protection of **meat** and poultry products? How does industry measure the performance of these systems?
** What in-plant...

LEGAL PUBLICATIONS:
... Pub. Law 59-242 SEC. 10 -- Department of Agriculture Appropriations Act, 1908; Federal **Meat** Inspection Act of 1907
19970610

17/K/30 (Item 4 from file: 180)
DIALOG(R)File 180:Federal Register

DIALOG Accession Number: 02374119 Supplier Number: 961101955
Transportation and Storage Requirements for Potentially Hazardous Foods
Volume: 61 Issue: 227 Page: 59372
CITATION NUMBER: 61 FR 59372
Date: FRIDAY, NOVEMBER 22, 1996

...AGENCY: **Food** Safety and Inspection Service...

... **Food** and Drug Administration...

...Center for **Food** Safety and Applied Nutrition...

...Office for **Food** Safety

SUMMARY: The **Food** Safety and Inspection Service (FSIS) and the **Food** and Drug Administration (FDA) are seeking information and comments on approaches the two Agencies might take to foster **food** safety improvements that may be needed in the transportation and storage of potentially hazardous foods. Potentially hazardous foods, including **meat**, poultry, eggs and egg products, fish, seafood, and dairy products, are those that are capable...

TEXT:
DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 325, 381

(Docket No. 95-049A)

RIN 0583-AC05

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 110

Transportation and Storage Requirements for Potentially Hazardous Foods

AGENCIES: **Food** Safety and Inspection Service, USDA; **Food** and Drug Administration, DHHS.

ACTION: Advance notice of proposed rulemaking; request for comments.

SUMMARY: The **Food** Safety and Inspection Service (FSIS) and the **Food** and Drug Administration (FDA) are seeking information and comments on approaches the two Agencies might take to foster **food** safety improvements that may be needed in the transportation and storage of potentially hazardous foods. Potentially hazardous foods, including **meat** , poultry, eggs and egg products, fish, seafood, and dairy products, are those that are capable...

... of written comments to: FSIS Docket Clerk, DOCKET #95-049A, Room 3806, South Agriculture Building, **Food** Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. All comments submitted...

... FURTHER INFORMATION CONTACT: Mr. Ralph Stafko, Office of the Administrator, Room 3835, South Agriculture Building, **Food** Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC, 20250, (202) 720-7773, in regard to **meat** , poultry, and egg products.

Ms. Shellee Davis, Center for **Food** Safety and Applied Nutrition (HFS-306), **Food** and Drug Administration, U.S. Department of Health and Human Services, 200 C Street SW...

... foods distributed in interstate commerce are not adulterated or misbranded. FSIS's programs, which cover **meat** , poultry, and egg products, include continuous in-plant inspection of livestock and poultry slaughtering, and...

...in most other circumstances, operates a regulatory program that includes unannounced inspection of the domestic **food** industry and sample analysis. FSIS conducts its inspections at **meat** , poultry, and egg product processing establishments.
FDA inspects establishments that process other types of foods...

...programs, and consumer education.

Both FSIS and FDA, in recent rulemakings, have adopted a new **food** safety regulatory strategy, the framework of which is a science-based system known as the hazard analysis and critical control points (**HACCP**) system. **HACCP** is a process control system designed to identify and prevent chemical, physical, and biological hazards in **food** production. On December 18, 1995, FDA published a final rule, "Procedures for the Safe and...

... Importing of Fish and Fishery Products" (60 FR 65096), mandating the development and implementation of **HACCP** systems to ensure the safe and sanitary processing and importation of fishery products. FSIS promulgated a final rule "Pathogen Reduction; **HACCP** Systems" for **meat** and poultry on July 25, 1996 (61 FR 38806) mandating implementation of **HACCP** systems and standard operating procedures (SOP) for sanitation, and pathogen reduction performance standards and testing for **meat** and poultry.

Both Agencies have come to recognize that, if they are to reduce foodborne illness to the maximum extent possible, they must broadly approach their **food** safety missions, addressing potential hazards that arise throughout the **food** production and delivery system. They and the industries they regulate must work toward preventing, minimizing...

... arise before raw products or animals enter manufacturing plants or FSIS-inspected establishments and after **food** products leave those businesses. There is widespread agreement among **food** safety experts that ensuring **food** safety requires taking steps to prevent hazards and to reduce the risk of foodborne illness...

... Post-harvest (seafood) and post-processing transporters, storage operators, and retail stores, restaurants, and other **food** service sectors are important links in the chain of responsibility for **food** safety. In these areas, FSIS, FDA, and State and local governments share authority and responsibility for oversight of **food** products. FSIS and FDA do not have programs that address the handling of **food** by these industry sectors, as they do for federally inspected processing establishments. However, both

Agencies...

... public health impact of diseases associated with potentially hazardous foods and about what happens to **food** at the stages through which it passes on the way to consumers.

This notice addresses...

... and Storage of Potentially Hazardous Foods: Current Regulatory Coverage and Guidance

Foods are susceptible to **contamination** from a wide variety of agents--physical, microbial, or chemical. Some foods, most notably animal **food** products like **meat** , poultry, eggs, seafood, and dairy products are particularly susceptible to microbiological hazards because their moisture ...

...microbiological, as well as other hazards.

No matter how carefully prepared, however, most any raw **food** product of animal origin may potentially have some bacteria present, including pathogens, and, ... minimizes the opportunity for bacteria to multiply. Furthermore, like other foods, these foods may become **contaminated** through direct abuse such as damaged packaging, exposure to filth or harmful chemicals, or contact with a **contaminated** surface. Sometimes, **contamination** is caused by direct or indirect contact with **contaminated** foods--a process known as cross- **contamination** . For example, salad components prepared on a cutting board used previously for raw poultry could become **contaminated** by pathogens that were on the poultry.

Food safety protection can be improved by the control of microbiological and other hazards through the use of preventive methods such as **HACCP** , good sanitation and manufacturing practices, and **food** safety performance standards, as appropriate, throughout the **food** production and **distribution chain** . Currently, however, most Federal regulatory measures are directed at slaughtering and **food** processing plants. State and local authorities have also directed their regulatory oversight at certain categories of **food** processors, generally small firms, as well as retail stores and **food** service establishments.

Despite increasing concern about the risks that may be created in the transportation...

... not have comprehensive regulatory programs for those segments of the farm (or harvest)-to-table **food** continuum that are comparable to that for slaughtering and processing establishments. Additional information is needed on the extent and severity of **food** safety problems that may be attributable to the transportation and storage of potentially hazardous **food** products from harvesting or production to processing plants and from processing plants to the consumer...

... for additional government regulation to address risks that may be created during these stages of **food** distribution.

1. FSIS

All ingredients used in **meat** and poultry products prepared in establishments where FSIS maintains inspection ("official establishments") are subject to...

... preparation of egg products at FSIS- inspected plants ("official plants") are also subject to inspection. **Meat** and poultry carcasses and parts that enter official establishments are inspected before they may be used in the preparation of **meat** or poultry **food** products at such establishments, regardless of whether they previously have been inspected and passed by...

...reinspection upon arrival at an official egg products processing plant.

The safety and wholesomeness of **meat** and poultry products being

transported in interstate commerce, or being held in storage, are governed ...

... and statutory provisions. Certain regulations (9 CFR part 325 and part 381 subpart S) require **meat** and poultry products being transported to be "wrapped, packaged, or otherwise enclosed" so as to prevent their adulteration by air **contaminants** , unless the means of conveyance in which the product is transported is completely enclosed with...

... removed from the means of conveyance prior to its use. Means of conveyance onto which **meat** or poultry products are loaded, being loaded, or intended to be loaded are subject to...

... a means of conveyance, upon inspection, is found to be in a condition such that **meat** or poultry products placed in it could become adulterated, it is not to be used until the condition that could cause adulteration is corrected. **Meat** and poultry products found by an inspector to be in such a condition that they...

... Sanitation Handbook, also presents details on acceptable conditions for transport vehicles and storage facilities of **meat** and poultry products.

FSIS monitors and enforces compliance with the adulteration and misbranding provisions of the Federal **Meat** Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) during transportation to and among inspected establishments and allied industries, such as renderers, pet **food** processors, retail stores, and restaurants. **Meat** and poultry products are considered to be adulterated for various reasons including if they are unsound, unhealthful, unwholesome, or otherwise unfit for human **food** (21 U.S.C.
453(g), 601(m)). Misbranding of **meat** and poultry products occurs, if among other reasons, their labeling is false or misleading. (21...

...1036.)
FSIS also investigates complaints received from consumers and others alleging that adulterated or misbranded **meat** , poultry, and egg products have been sold or distributed in commerce.

FSIS has exercised its statutory authority over **meat** and poultry products outside official establishments in various instances, including in its promulgation of safe-handling labels on raw **meat** and poultry products (9 CFR 317.2(l) and (m), and 381.125(b)). However, FSIS does not have a comprehensive regulatory program that covers the handling of **meat** , poultry, and egg products outside of official establishments that is comparable to its program of...

... outside official establishments. FSIS has not focused directly on conditions and practices that occur after **meat** , poultry, and egg products leave official establishments that contribute to products being exposed to pathogenic **contaminants** , or that contribute to the multiplication of pathogenic microbes.

FSIS-inspected product that is in... examines specific conditions to determine the adequacy of warehouse procedures for preventing the adulteration of **meat** and poultry products, including the adequacy of sanitation at the warehouse and the other controls utilized to reduce hazards, such as pests, to **meat** and poultry products.

Post-processing transportation and storage of **meat** and poultry products was also a subject of concern to commenters on FSIS's February 3, 1995, Pathogen Reduction/ **HACCP** proposal. Various commenters stated that the majority of hazards consumers face from raw **meat** and poultry products stem from mishandling the products after they have left the official establishments...

...further stated that FSIS should expand its inspection program to include all segments of the **food** production and transportation industries. Some commenters noted that, although there is not a sufficient number...

... there must be some additional regulatory efforts to ensure proper controls are maintained throughout the **food** chain.
Other commenters stated that they believed that transportation and storage entities should not be subject to regulatory controls. They stated that warehousing and **food** distribution operations do not pose the same levels of risk as processing operations. Still others...

... should develop voluntary guidelines for transport conveyance, not mandatory requirements.

2. FDA

FDA routinely inspects **food** processing plants and examines **food** products transported in interstate commerce. The examination and inspectional aspects of FDA's program are...

... as part of its compliance program for foods. FDA covers the full range of potential **food** safety problems, including microbial hazards, chemical **contaminants** , pesticides, filth, and **food** additives. FDA provides similar coverage for imported foods.

FDA's requirements for the conditions under which **food** is to be transported and stored are contained in FDA's good manufacturing practice regulations (21 CFR Part 110). The conditions under which **food** is received, inspected, transported, segregated, prepared, manufactured, packaged, and stored of **food** must be such as to ensure that the **food** will not become **contaminated** with filth or rendered injurious to health. Storage and transportation of finished **food** must be under conditions that will protect **food** against physical, chemical, and microbial **contamination** , as well as against the deterioration of the **food** and its container (21 CFR 110.93).

FDA's final rule on seafood, which mandates the application of **HACCP** principles to the processing of seafood, is designed to ensure that the hazards that are presented at all stages of the **food** processing and **distribution chain** , including transportation, are identified, and appropriate control measures are put in place to address them. Thus, for example, a processor could require, as part of its **HACCP** plan, that a certain temperature be maintained during the transport of raw materials to its...

... whether to require a comprehensive preventive regulatory program, similar to its seafood regulatory program, for **food** products other than seafood in commerce. On August 4, 1994, FDA published an advance notice of proposed rulemaking entitled "Development of Hazard Analysis Critical Control Points for the **Food** Industry" (59 FR 39888), which sought public comment on whether and how FDA should develop regulations to establish requirements for a new, comprehensive, **food** safety assurance program for both domestically produced and imported foods. Further regulatory action by FDA...

... is used exclusively in the carriage of poisonous materials (49 CFR 174.615(b)).

4. **Food** Code

Finally, the transportation and storage of **food** products is dealt with in the **model** **Food** Code, which is published by FDA. This **model** code contains provisions that specifically address the storage and preparation of foods at retail stores...

... It also contains recommended holding temperatures for a variety of foods. Most State and local **food** statutes, regulations, and ordinances are based on some edition of FDA's **model** **food** code.

Risk of **Contamination** and Disease From **Food** Transportation

1. Current Transportation Vehicles and Conditions

There are three basic types of ...transport, which consists of rail cars and trucks. Of the approximately 47 million tons of **food** shipped between continents each year, about 60 percent goes by sea, 35 percent by land, and 5 percent by air. Approximately 22 million tons of **meat** and poultry, fish, and dairy products are exported intercontinentally each year, with 40 percent of...

... seaports and rail heads to the ultimate consumer. Thus, it is assumed that most refrigerated **food** cargo, whether originating overseas or within the U.S., ultimately travels by truck transport.

2. Safeguarding **Food** Under Conditions of Transport, e.g., the "Cold Chain"

The logistics of moving perishable, potentially...

...oysters.

3. Technical Analysis Group (TAG) Report on Transportation

When FSIS proposed the Pathogen Reduction/ **HACCP** rule in February 1995 (60 FR 6774), FSIS stated its commitment to develop standards to help ensure the safe handling of **meat** and poultry products during transportation and storage.

FSIS stated it would: (1) Ask a group of experts to provide data on the hazards to **food** safety and the controls that currently exist in the industry to address such hazards; (2) develop practical standards of performance for establishments and carriers with respect to the transport of **food** ; (3) develop a list of good manufacturing practices and various options for encouraging their use...

... where feasible, joint rulemaking with FDA to establish appropriate standards to ensure the safety of **meat** and poultry products and other foods during transport, and (5) along with FDA, work with the DOT to implement the Sanitary **Food** Transportation Act of 1990, as revised, and determine whether additional authority is needed to carry out the shared **food** safety mission of FDA and FSIS. (Id., at p. 6828)

In April 1995, FSIS and...

... of perishable foods and recommend reasonable controls that might be employed by industry to ensure **food** safety. The 10-member TAG was composed of representatives from academia, the transportation and **food** industries, and DOT. The TAG's tasks were to identify hazards associated with the transportation...

... formulating good manufacturing practices (industry guidance) or regulations, or both, dealing with the transportation of **meat** , poultry, and egg products.

Tasks of the TAG for **meat** , poultry, and egg products included: (1) Identifying and describing the steps comprising the transportation of...

... of time and money kept the TAG from inquiring much into the state of perishable **food** transport by air, sea, or rail. Therefore, FSIS would appreciate having information and comments from...

... found that how trucks are loaded has a very direct relation to the likelihood of **food** **contamination** and abuse. A less-than-full-load (LTL) is a truck that has available space... likely to haul smaller, mixed cargoes.

LTL and mixed loads may be troublesome from the **food** safety standpoint for several reasons. First, such a load may consist of foods with different ...

... The temperature of the trailer or container with the load may be suitable for one **food** but not for another. An extreme example of this

problem would be an LTL or mixed load maintained at a refrigeration temperature but in which part of the **food** cargo must be kept frozen. Some freight companies have solved this problem by using partitioned...

... different temperature, so the LTL holding temperature problem does not arise.

Another hazard to which **food** carried in LTL containers may be exposed is the failure to maintain the proper storage...

... and unloaded more frequently during a trip, it is technologically more difficult to consistently maintain **food** cargo at the correct temperature than it is for uniform **food** cargo carried to a single destination. Each time freight is loaded or unloaded, the opportunity exists, even under the best of handling conditions, for a temperature fluctuation that may cause **food** safety problems.

A further problem that can arise is potential adulteration of **food** cargoes by incompatible **food** or non- **food** cargoes. For example, some cargoes may release gases or odors that are absorbed by other...

... refrigeration units, air circulation, humidity, insulation of trucks, and the time taken to transport the **food** .

The TAG concluded that good controls are essential to ensuring safe transportation of perishable foods...

... F temperature while awaiting additional product to be loaded; (5) maintaining the temperature of the **food** during transit; and (6) maintaining the inside temperature of the **food** during unloading and movement to storage. For each of these critical control points, the TAG...

... FDA are concerned about whether reliable procedures are being used by all sectors of the **food** production and delivery chain to combat the invisible threats to safety and health posed by...

... and other regulatory and public health measures are applied most intensively, as in slaughterhouses, and **food** processing facilities.

Agencies concerned with **food** safety have devoted relatively few resources to the transportation and storage sectors of the **food** chain. There is an absence of data and information about whether adequate and appropriate **food** safety controls are being employed while **food** is being transported and stored. This lack of information does not by itself indicate the...

... warranting regulatory intervention. However, FSIS and FDA need information about the transportation and storage of **food** if they are going to assure that the **food** safety risks associated with transportation and storage are properly identified and adequately addressed.

The United...

... million foodborne illness cases. These are largely associated with potentially hazardous foods that have become **contaminated** . In most cases of foodborne illness, post-processing temperature abuse or other mishandling contributed to the **food** hazard implicated in the illness. Such mishandling of potentially hazardous foods frequently occurs in **food** -service establishments and homes.
However, **food** product abuse also may occur at earlier stages. In processing establishments, for example, equipment breakdowns, failure to adhere to appropriate time and temperature requirements, cross- **contamination** between raw and cooked product, and physical **contamination** by chemicals or foreign matter may render foods unsafe.

Although there is little empirical data on the extent to which conditions under which **food** is transported and stored contribute to safety hazards, there is anecdotal evidence. For example, a...

... 224,000 people is believed by public health authorities to have been caused by cross- **contamination** of a pasteurized ice cream premix during transportation in tanker trailers that had previously hauled...

...Ice Cream. N. Engl. J. Med. 334:1281- 1286.

FSIS, in its continuous inspection of **meat** and poultry establishments, has found that some **food** spoilage can be attributed to mishandling during transportation, based on examination by inspectors of **meat** and poultry products returned to official establishments ("returned product") that have been refused by a...may be in transportation channels, but the Agencies do not know how much potentially hazardous **food** that is spoiled is returned or otherwise handled.

Only a very small percentage of **meat** or poultry product that is shipped from a federally inspected establishment is returned to the...

...returned because of a problem that developed during transportation. This seems generally true for imported **meat** and poultry products, as well as domestically produced products. In 1994, FSIS rejected nearly 14 million pounds (0.5 percent) of imported **meat** and poultry products, most commonly for processing defects, **contamination** , unsound condition, and transportation damage. This rejection rate is roughly equivalent to the rejection rate...

...of unwholesome or misbranded product.

From time to time, foreign countries to which U.S. **meat** and poultry exports are sent have rejected U.S. product that has become spoiled because ...

... accept shipments of United States-produced poultry alleged to be "off-condition" and unfit for **food** purposes. The poultry had apparently been allowed to thaw at some point between shipment from...
...years earlier.

Similarly, there have been occasional, documented instances of careless handling and transportation of **meat** and poultry within the U.S. These generally involve inadequate refrigeration or exposure to physical hazards.

There appears to be increasing public awareness of the possibility that **food** might become **contaminated** during shipment. From time to time, Congress has expressed concern that gaps in the regulatory coverage of **food** during transportation in commerce ought to be filled. For example, in 1990 Congress passed the "Sanitary **Food** Transportation Act" that required the Secretary of Transportation, in consultation with the Secretaries of Agriculture...

... Administrator of the Environmental Protection Agency, to issue regulations with respect to the transportation of **food** products in motor vehicles or rail vehicles that are also used to transport nonfood products that could make **food** subsequently shipped in the vehicles unsafe.2 (Pub. L. 101-500; 49 U.S.C...

... on the extent of the practice was scarce, there were press accounts of trucks carrying **food** from the Midwest to both the East and the West Coasts and returning with garbage for Midwest landfills. It was feared that **food** products could become **contaminated** and unfit for human consumption if irresponsible vehicle operators failed to prevent **contamination** of **food** products in vehicles that had been previously used to haul waste or other non- **food** materials.

Note 2 In July 1994, Congress passed Public Law 103-272, which revised Title 49 of the U.S. Code, including provisions for Sanitary **Food** Transportation (Chapter 57--Sanitary **Food** Transportation. (49 U.S.C. 5701 to 5714.)

On May 21, 1993, DOT proposed regulations to implement the new law. The

proposal addressed the safe transportation of **food** products during highway and rail transportation (58 FR 29698). Further action on the proposal is...

... and FDA are now attempting to develop better information on the nature and scope of **food** safety risks posed by transportation and storage practices.
The Agencies would like, among other things...

... information about what controls are currently being used to ensure the safety of potentially hazardous **food** during transportation, for truck, rail car, airplane, or ship transports.

Additionally, the Agencies would like...

...but more precise information is needed.

Information and Accountability; Failure of the Market

Most large **food** companies conduct rigorous quality control operations to ensure, among other things, that the foods and **food** ingredients they purchase match contract specifications and will be suitable for use in the manufacture of their products. Many companies already operate **HACCP** systems to ensure the safety of the **food** products that they deliver to consumers.

Such companies enforce their own criteria for foods and **food** ingredients delivered to them. If refrigerated or frozen foods arrive at the receiving departments of...element of this market failure is lack of information for purchasers. Purchasers of potentially hazardous **food** products may lack information about products other than their appearance.
Signs of spoilage, such as...

... because some pathogens do not cause illness until several days or weeks after exposure. Thus, **food** safety attributes are often not apparent to consumers either before purchase or immediately after consumption of **food**. This information deficit also applies to wholesalers and retailers who generally rely on sensory tests--sight and smell--to determine whether a **food** is safe to sell or serve. Therefore, if **food** became **contaminated** because of a problem in transportation or storage, the receivers of the **food** might not know about it and might not be able to relate a resultant outbreak of foodborne illness to the problem.

Applicable Legal Authorities

Both the Federal **Meat** Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection...

... 21 U.S.C. 451 et seq.) give the Secretary of Agriculture authority to regulate **meat** and poultry products in commerce. Specifically, the FMIA and PPIA authorize the Secretary to prescribe regulations covering the storage or other handling of **meat** or poultry products whenever the Secretary determines that regulations are necessary to assure that **meat** or poultry products are not adulterated or misbranded when they are delivered to the consumer...

... may "sell, transport, offer for sale or transportation, or receive for transportation" in commerce any **meat** or poultry product that is capable of use as human **food** and is "adulterated or misbranded at the time of such sale, transportation, offer for sale...

...of adulterated or misbranded eggs or egg products (21 U.S.C. 1037).

The Federal **Food**, Drug, and Cosmetic Act (FFD&C Act), administered by FDA, prohibits the adulteration or misbranding of **food** in interstate commerce (21 U.S.C. 331(b)). The FFD&C Act also prohibits...

...for introduction into interstate commerce, and the receipt in interstate commerce, of adulterated or misbranded **food** (21 U.S.C. 331(a) and (c)). Section 402(a)(4) provides that a **food** is deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become **contaminated** with filth, or whereby it may have been rendered injurious to health (21 U.S...
... animal host, vector, or the inanimate environment (21 CFR 1240.3(b)). With respect to **food** as a vector (carrier), infectious agents include Listeria monocytogenes, Salmonella enteritidis, Vibrio vulnificus, and similar...

... in interstate commerce, including regulations governing the transportation and storage of such foods.

The Sanitary **Food** Transportation provision also provides authority to regulate the transportation of **food** (49 U.S.C. 5701 to 5714). However, FSIS and FDA regard some of the potential **food** safety issues associated with previous cargoes as involving more than just nonfood products regulated by...

... just nonfood products. Thus, this ANPR seeks information on the appropriate mechanism for addressing prior **food** cargoes. FSIS and FDA seek comment on how DOT requirements for **food** transportation conveyances that also haul nonfood items, under its Sanitary **Food** Transportation statutory provisions, might be complemented by additional FSIS/FDA requirements.

FSIS and FDA believe and storage are vital links in the farm (or seafood harvest)-to-table **food** chain, the success of a comprehensive, farm (or harvest)-to-table **food** protection strategy requires that effective preventive measures be taken to ensure the safe transportation and storage of **food** . FSIS and FDA are considering several alternatives for addressing the safety of potentially hazardous foods...

... These alternatives include specific requirements, such as temperature standards, performance standards, recordkeeping to ensure that **food** safety controls are maintained, mandatory **HACCP** -type systems, voluntary guidelines, and combined approaches.

Regardless of the alternative, one constant is the need for personnel who understand the importance of handling **food** cargoes safely and who know how to do it. All persons involved in transporting and storing foods need to recognize that **contaminated** foods can cause illness and that microbes can spoil or poison foods. It is important...

... to and maintained at or below a specific temperature during transportation and storage from the **food** processing plant to the retail outlet, restaurant, or other establishment serving the consumer. If this approach is adopted, all potentially hazardous foods being transported to retail or **food** service establishments would have to be maintained at or below such a maximum temperature.

In its February 1995 Pathogen Reduction/ **HACCP** proposal, FSIS proposed various requirements for chilling and cooling **meat** and poultry products. The proposal included specific time and temperature parameters for the rate of cooling **meat** and poultry carcasses in slaughtering establishments and a maximum shipping temperature of 40 deg.F for raw **meat** and poultry products leaving FSIS-inspected establishments. FSIS agreed with commenters that keeping raw products...

...is 41 deg.F.
This standard is consistent with the temperature recommended by the 1995 **Food** Code for cooling and holding (including during transportation) potentially hazardous **food** . It would provide a margin of safety to prevent the multiplication of pathogenic bacteria, which...

... the temperature established by the European Union 3 for the transportation, in commerce, of raw **meat** products. This temperature is increasingly accepted as a standard for potentially hazardous foods during

storage...

... impose significant costs, especially on small business entities, but achieve no clear public gains in **food** safety protection. Available evidence indicates that the key factor in determining bacterial growth in shell...

... temperature requirements for shell eggs is similar to its approach to the cooling of red **meat** carcasses.
FSIS has decided that before it can impose temperature requirements, it must have better data and information on the **food** safety effects of temperature controls at all phases of production and distribution.

Temperature-based performance...

... be complemented by some requirement that would permit processors to determine the acceptability of a **food** transport vehicle for the transport of bulk foods that pose a risk of communicable disease...

... anticipate that Federal standards governing proper transportation and storage for potentially hazardous foods and other **food** safety practices would be, to some extent, self-enforcing. In the view of FSIS and...

... on the extent to which such Federal standards are likely to achieve and safeguard public **food** safety objectives with a minimal enforcement effort.

The merits of any temperature standards, and alternative...

... of being vectors for the spread of communicable disease are transported interstate, to help prevent **contamination** and cross- **contamination** of certain **food** cargoes. ...carriers of potentially hazardous foods that are shipped in bulk (foods which directly contact a **food** conveyance) to provide **food** shippers with records that identify the last three cargoes for any conveyance being offered to the **food** shipper for use in transporting the **food** and that disclose the data of the most recent cleaning of the conveyance.

FDA and...

... and effectiveness of this approach for ensuring the availability of information needed to assess potential **contamination** from prior cargoes in a transportation vehicle.

3. Mandatory **HACCP** -type Systems
Another approach that could be taken would be to require that a **HACCP** system be established specifically with respect to the transportation and storage of potentially hazardous foods to prevent the **contamination** of these foods, although, as noted earlier, comments on the FDA and FSIS **HACCP** rulemakings were negative on requiring **HACCP** for transportation and storage.
Such requirements could be modeled on the regulations recently adopted by FSIS and FDA that apply to establishments that process **meat** , poultry, and seafood.

Such **HACCP** -type systems would probably be relatively simple. Essentially, they would likely require that potentially hazardous...

... use of a temperature performance standard would allow processors to determine the acceptability of a **food** transport vehicle for the transport of certain bulk foods, i.e., those that pose a risk of communicable disease, based on cargo records.

Personnel involved in the implementation of the **HACCP** -type systems would have to be knowledgeable about product vulnerabilities and be trained in **HACCP** principles, the development, reassessment, and modification of **HACCP** plans, and record review. If this option were pursued, the Agencies would consider the development of **model** **HACCP** plans or other guidelines

that could be used by transportation and storage companies in developing their own **HACCP** plans.

4. Voluntary Guidelines

Another approach under consideration is to make more use of voluntary...

... frozen. Such guidelines could serve as the basis for developing joint Government-industry guidelines for **food** transportation and storage.

For example, the Association of **Food** and Drug Officials (AFDO), a voluntary organization of State and local **food** regulatory officials, in its publication entitled "Guideline for the Transportation of **Food** ," states that during transportation, potentially hazardous **food** should be maintained at 45 deg.F or below. The AFDO guideline states that frozen **food** should be held at an air temperature of 0 deg.F or below and should ...

... recording device is recommended for measuring air temperature in the transportation vehicle. Maintaining the proper **food** temperature is one of AFDO's four major **food** transportation measures for ensuring **food** safety. The remaining measures cover the use of good sanitation practices, good personal hygiene of **food** employees, and adequate transportation equipment.

The Frozen **Food** Round Table, a trade organization, in its publication entitled "Frozen **Food** Handling and Merchandizing" presents several recommended practices for transporting and storing frozen foods. These practices...

... Perishable Foods During Transport by Truck." The handbook contains recommendations for loading and transporting various **food** commodities. In the handbook, AMS states that maintaining the desired or ideal holding temperature is...

... against quality loss during transportation and storage. The handbook also presents recommended temperatures for holding **meat** , poultry, fresh fish, and other commodities during transportation.

The Interstate Shellfish Sanitation Commission also has...

... is carrying out a long- term strategy for ensuring product safety that focuses primarily on **HACCP** but that also depends for its effectiveness on a series of prerequisite good manufacturing practices...

... The association has developed a manual that is product-oriented and product-specific and contains **model** **HACCP** programs for such product categories as fluid milk, ice cream, cheese, and yogurt.

Finally, the **HACCP** systems that have been implemented voluntarily by some major **food** service companies provide time, temperature, sanitation, and **contamination** critical limits to be applied at critical control points such as at shipping and receiving...

... above- discussed approaches. For example, time/temperature performance standards could be required along with mandatory **HACCP** -type systems. By specifying critical limits--such as the maximum temperature--to be met in ...

... among processors in measures that they take to ensure the safety and quality of that **food** while it is being transported and stored.

The combination of a performance standard, such as... specific time/temperature recommendations or cargo handling procedures intended to prevent physical, biological, or chemical **contamination** . Some involve the voluntary implementation of **HACCP** systems. The voluntary guidelines therefore cover many of the recommendations considered in this ANPR as...

... effective adoption of the guidelines by transportation and storage facilities and the consequent achievement of **food** safety goals.

6. Alternative of No Federal Regulatory Initiative

This alternative would mean that the...

... laws and regulations. Both Agencies have the authority to detain or seize adulterated and misbranded **food** products that are in interstate commerce. The Agencies could, for example, take action on a cargo of potentially hazardous **food** that is found to be in an off-condition, that is **contaminated** with some deleterious substance, or that is being held at too high a temperature. Depending on the type of cargo, the **food** could be detained based on evidence of adulteration and be allowed to be returned to ...

... subject to Government seizure. However, actions of this sort are inefficient ways to encourage safe **food** handling practices and can involve the Agencies and **food** companies in costly court actions. Worse, they are merely reactive. Although they may have some...

...address the underlying causes of the problem.

The Agencies could, and would, continue to promote **food** safety practices through public information and consumer education, directing their efforts, to the extent possible and appropriate, to **food** transporters and storage facility operators. The effectiveness of these efforts, however, would depend on the industry also being an advocate for good **food** storage and handling practices and comprehensive preventive approaches.

Comparison of Alternatives

FSIS and FDA would...

... hazardous foods? Which of the alternatives is both feasible and is most likely to prevent **food** safety hazards from arising during transportation and storage? Which would be most effective and which...
... would allow industry the greatest flexibility in adopting technologies or developing other means to prevent **food** safety hazards or reduce the likelihood they will occur? Which would be most likely to...

... the consequent need to ensure that all public resources devoted to the common goal of **food** safety are used in a coordinated way that maximizes public health protection while minimizing public...

... of a larger proportion of the Agencies' resources to monitoring the transportation and storage of **food** , compared with resources presently allocated to those activities. Assuming at best no real growth in...

... necessary to shift resources from in-plant inspection and other activities to the examination of **food** transportation and storage. Reallocations of personnel would entail judgments on the benefits of making new...

... consumers that derive from transportation and storage operations, compared with the risks that derive from **food** processing and other activities.

Thus, for example, new information may dictate that FDA and FSIS...
... to verify compliance with any requirements that apply to the conditions under which potentially hazardous **food** is transported by land, air, or sea, or is stored.

Therefore, the agencies would appreciate...

...resources. That is, assuming that the general goal of the Agencies is to achieve maximum **food** safety protections throughout the farm

(pre-harvest)-to-table continuum, is it reasonable for the...

... more than a part of the solution. The primary responsibility for protecting the safety of **food** products in distribution channels rests with those in that business--in this case, those who institute a **HACCP** -type system or other control system where such systems are not already in operation would...

... on the control or reduction in microbial populations that the application of new technologies could **produce** .
Of special value would be information relating to predictive modeling of time, temperature, and microbial...

...which the technologies might be applied.

The costs to the Agencies of increased oversight over **food** transportation and storage would include costs associated with increases in personnel travel, costs for training...

... be additional tangible and intangible benefits. For some companies, increased reliance on quality control or **HACCP** -type systems could result in improved product tracking and inventory control, reduction in product loss, and overall efficiency gains. An intangible benefit, increased confidence in the **food** supply among both domestic and foreign purchasers, could lead to indirect tangible benefits for processors...

...foodborne illnesses that can be directly or indirectly attributed to the transportation of potentially hazardous **food** .

The Agencies also need information about the businesses that may be affected by any of...small entities under the RFA. Businesses of concern would include establishments that process and ship **meat** , poultry, eggs, seafood, and other potentially hazardous foods, motor freight companies, **food** storage warehousing operations, air freight companies, and water transport firms.
Under the Small Business Administration...

...more than 1,500 employees.
A small entity in the categories of water transportation or **food** processing is one that employs no more than 500 people.

Finally, the agencies are requesting...

... energy consumption that may result either from the need to increase refrigeration during transportation of **food** or from the use of more trucks to avoid transporting **food** in trucks that had previously held cargoes that could affect **food** safety, (2) increased disposal of defective foods, (3) new or increased use and disposal of...

...from this action.

Done at Washington, DC, on: November 18, 1996.

Thomas J. Billy,
Administrator, **Food** Safety and Inspection Service.

William B. Schultz,
Deputy Commissioner for Policy, **Food** and Drug Administration.

(FR Doc. 96-29837 Filed 11-18-96; 5:08 pm)

BILLING...

LEGAL PUBLICATIONS:
...Pub. Law 90-201 SEC. 2 13 15 -- Federal **Meat** Inspection Act of 1967

...

... Law 59-242 SEC. 1 24 10 301 -- Department of Agriculture Appropriations Act, 1908; Federal **Meat** Inspection Act of 1907...

...Pub. Law 101-500 -- Sanitary **Food** Transportation Act of 1990; Motor Carrier Safety Act of 1990...

...Pub. Law 75-717 SEC. 301 701 402 -- Federal **Food** , Drug and Cosmetic Act (Act of 6/25/38)
19961122

17/K/31 (Item 5 from file: 180)
DIALOG(R)File 180:Federal Register

DIALOG Accession Number: 02369327 Supplier Number: 951201444
Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products
Volume: 60 Issue: 242 Page: 65096
CITATION NUMBER: 60 FR 65096
Date: MONDAY, DECEMBER 18, 1995

...AGENCY: **Food** and Drug Administration...

...Center for **Food** Safety and Applied Nutrition

SUMMARY: The **Food** and Drug Administration (FDA) is adopting final regulations to ensure the safe and sanitary processing...

... seafood), including imported seafood. The regulations mandate the application of Hazard Analysis Critical Control Point (**HACCP**) principles to the processing of seafood. **HACCP** is a preventive system of hazard control that can be used by processors to ensure...

TEXT:
... grouping would reduce the paperwork burden on some processors without altering the benefits attainable through **HACCP** .

FDA agrees with the suggestion for the reason presented by the comments and has modified Sec. 123.6(b) accordingly, to read, in part:

A **HACCP** plan shall be specific to: (1) Each location where fish and fishery products are processed...

... of fish and fishery products together, or group kinds of production methods together, if the **food** safety hazards, critical control points, critical limits, and procedures required to be identified and performed...

...or for all production methods so grouped.

60. In the proposal, FDA specified that a **HACCP** plan must identify: The applicable **food** safety hazards; the CCP's; the CL's; the control and monitoring procedures; and the...
...include" rather than "identify" to describe a requirement for an item to appear in the **HACCP** plan. The comments suggested that it is not clear from the word "identify" whether the...

...to their existence in a guideline or other source.

FDA's intent is that a **HACCP** plan explicitly include the value or a description of the procedures for each of the required **HACCP** elements. FDA agrees that a word such as "list" would be less ambiguous. Therefore, FDA... the comments in part. FDA's intent was to require control of decomposition in a **HACCP** plan only when it represents a **food** safety hazard. As described in the preamble to the proposed regulations, histamine (scombroid toxin) development as a result of microbiological decomposition

in certain species of fish is a well recognized **food** safety hazard (Ref. 5, p.
24). There are some early indications, however, that the development...

... putrescine and cadaverine, also byproducts of decomposition of fish, under certain circumstances, may also represent **food** safety hazards (Ref. 203, p.
240). For this reason, FDA is hesitant to limit the...
... to read, "Decomposition in scombroid toxin- forming species or in any other species where a **food** safety hazard has been associated with decomposition."
62. Comments from two State government agencies and...

... parasites as a safety hazard that must be considered for inclusion in a processor's **HACCP** plan. The comments noted that, with respect to pathogens, FDA makes the assumption that raw...

...retail level is appropriate point of control for parasites, and that the provisions of the **Food** Code are adequate to address this issue.

The comments further argued that parasites pose a...

...sold for raw consumption.

FDA's intent is to require control of parasites in a **HACCP** plan only in those instances when parasites are reasonably likely to occur in the portion of the flesh that is consumed, and the presence of the parasites will present a **food** safety hazard (e.g., where the fish is offered for raw consumption).
To clarify this...
... 3, p. 267; and 7, p. 33). For this reason, sanitation controls designed to prevent **contamination** of fish flesh are important to minimize the levels of enteric pathogens found on processed...

... the presence of Salmonella on raw fish, based, in part, on the avoidability of such **contamination** through the application of CGMP's.

63. One comment stated that the term "physical hazards...

...hazards.

In Sec. 123.6(c), physical hazards are one of nine listed causes of " **food** safety hazards" that processors should consider for listing in their **HACCP** plans (Sec. 123.6(c)(1)(ix)). Thus, the agency believes that the language of this section clearly applies to **food** safety hazards only, and no modification of the provision is necessary in response to this comment.

FDA proposed that **HACCP** plans include the CL's that must be met at each CCP. FDA received no...

...c)(3)) and has made no substantive changes to it.
FDA proposed to require that **HACCP** plans include the procedures for both "monitoring" and "controlling" the CCP's. FDA recognizes that monitoring and controlling serve different purposes, and that the appropriate **HACCP** principle is the monitoring of CCP's to ensure conformance with the CL (Ref.
34.. . immediate feedback about whether the process is under control that monitoring should provide in a **HACCP** system. Consumer complaints may provide the processor with information that would be useful for verification...

...hazards (e.g., checking container tags and harvester licenses as a means of controlling microbiological **contamination** in molluscan shellfish, and checking vessel storage records as a means of controlling histamine development...

...the comments.

FDA has added Sec. 123.6(c)(5) that describes requirements of the **HACCP**

plan with regard to corrective actions. As explained in more detail in the "Corrective Actions...

...FDA has also added Sec. 123.6(c)(6), which describes the requirements of the **HACCP** plan with regard to verification. As explained in more detail in the "Verification" section of...

... has concluded in response to comments that a processor needs to specifically include in its **HACCP** plan the verification procedures that it will use and the frequency with which it will...

...processor and its employees as well as by regulatory officials.

FDA proposed to require that **HACCP** plans provide for a recordkeeping system that documents the monitoring of CCP's. The proposed...a large processor and a trade association stated that, based on their extensive experience with **HACCP** , positive monitoring records provide a pattern of results and values that is much more meaningful...

... firm management nor FDA could verify that the monitoring procedures specified in a processor's **HACCP** plan are being carried out if only records of deviations from CL's are kept...

... to help prevent unscrupulous processors from circumventing the system. An additional comment supported limiting mandatory **HACCP** recordkeeping to negative records because FDA could not rule out the possibility that future court decisions or changes in FDA policy might permit the disclosure of **HACCP** records in FDA's possession, and negative recordkeeping would reduce a company's potential exposure...

... of records. As the preamble to the proposed regulations noted, recordkeeping is the key to **HACCP** , enabling the processor and the regulator to see the operation through time. Negative records alone...

... is convinced that this minimal additional effort greatly increases the chances that a processor's **HACCP** program will be successful.

Based largely on FDA's experience with the positive recordkeeping requirements in the low-acid canned **food** and the acidified **food** industries, FDA does not agree that the volume of positive records that a system will... believes that most processors will quickly see the benefits to themselves of a properly operating **HACCP** system based on positive records and will insist that their records be accurately completed.

One such benefit should be a more motivated workforce. **HACCP** monitoring and recordkeeping can and should be done by the workers who operate the system...
...Plan

66. In the preamble to the proposed regulations, FDA specifically invited comment on whether **HACCP** plans should be required to be signed by a representative of the firm and, if...

...argued that a signature was unnecessary.

Those that favored a requirement for a signature on **HACCP** plans stated that the signature does the following: Demonstrates formal adoption of the **HACCP** plan, solidifies responsibility for adherence to the plan, and fosters a sense of management ownership...

... in order of preference): Onsite manager, most responsible individual of the firm, any senior manager, **HACCP** coordinator, and all **HACCP** team members. Those comments that argued against a mandatory signature on the plan stated that the existence of a **HACCP** plan itself constitutes management support for the plan.

FDA agrees with the comments that recommended a requirement for **HACCP** plans to be signed by a representative of the firm. As suggested by the comments...

... of management's acceptance of the plan for implementation. FDA cannot stress enough that for **HACCP** to succeed, there must be a clear commitment to it from the top of the...

... of this important responsibility and will signal to all employees that the firm regards the **HACCP** plan as a document to be taken seriously. Additionally, the representative's signature, along with...

...a new paragraph at Sec. 123.6(d), that reads:

(d) Signing and dating the **HACCP** plan. (1) The **HACCP** plan shall be signed and dated, either by the most responsible individual onsite at the ...

... shall signify that the plan has been accepted for implementation by the firm. (2) The **HACCP** plan shall be dated and signed: (i) Upon initial acceptance; (ii) Upon any modification; and...

... will be discussed fully in the "Verification" section of this preamble, the adequacy of the **HACCP** plan must be reassessed, and modified as needed, whenever significant changes in the firm's...
... regulations for these products under part 113, it would also be in compliance with these **HACCP** regulations with respect to the control of the hazard of C.
botulinum toxin production. The regulations at part 113 establish **HACCP** -type controls for this hazard.

FDA agrees that there is no need for a processor to restate in its **HACCP** plan the requirements of part 113 or 114. It is also not necessary for such ...

... requirements of part 113 or 114 need not address this hazard at all in their **HACCP** plans. However, it is important to note that other hazards may be reasonably likely to...

... an acidified or low-acid canned fishery product. These hazards must be addressed in the **HACCP** plan, as appropriate. For example, processors of canned tuna will likely need to identify in their **HACCP** plans how they will control the development of histamine before the canning process. Accordingly, to...

...that are subject to the requirements of part 113 or 114 of this chapter, the **HACCP** plan need not list the **food** safety hazard associated with the formation of Clostridium botulinum toxin in the finished, hermetically sealed container, nor list the controls to prevent that **food** safety hazard. A **HACCP** plan for such fish and fishery products shall address any other **food** safety hazards that are reasonably likely to occur.

9. Sanitation in the Plan

The question of the role of processing plant hygiene (i.e., traditional sanitation controls) in **HACCP** is addressed at length in the "Sanitation" section of this preamble. As explained in that...

... from critical control point monitoring activities, or by including sanitation controls as part of the **HACCP** plan, or by adopting some combination of these two approaches, at the option of the...

... in paragraph (f) in Sec. 123.6 on the inclusion of sanitation controls in the **HACCP** plan FDA has stated: "(f) Sanitation controls may be included in the **HACCP** plan. However, to the extent that they are monitoring in accordance with Sec. 123.11(b), they need not be included in the **HACCP** plan and vice versa."
FDA recognizes that, in many processing operations (e.g., cooked, ready... ... such as hand and equipment washing and sanitizing, are critical to the safety of the **food** because they serve to minimize the risk of pathogen introduction into finished products that may...

... some processors may elect to include the control of sanitation conditions and practices in their **HACCP** plan in addition to, or in place of, monitoring for such conditions and practices apart from the **HACCP** plan. Based in part on experience gained from the seafood **HACCP** pilot project operated jointly by FDA and DOC, however, FDA also recognizes that sanitation controls may be difficult to fit in **HACCP** plans, with appropriate CL's and corrective actions sometimes being elusive.
For this reason, some processors may elect to rely exclusively on sanitation controls that are not part of the **HACCP** plan. FDA considers either approach to be acceptable, so long as whatever approach is chosen...

...68. FDA proposed in Sec. 123.6(c) to recommend, but not to require, that **HACCP** plans include controls for such nonsafety hazards as economic adulteration and decomposition that are not...

... append to the regulations at Appendix D guidance on how a processor can use a **HACCP** -based approach to ensure that fish and fishery products are in compliance with the economic...
...to be included in the Guide.

Those that argued for removal of the recommendation that **HACCP** be used to control nonsafety hazards from the regulations stated that: (1) **HACCP** for safety purposes will be a big enough challenge for both the industry and regulators...

... in the same manner in which safety hazards are treated in these regulations, with mandatory **HACCP** controls. These comments argued that: the same conditions of processing that affect the occurrence of...as in the case of the substitution of a scombroid species for a nonscombroid species; **HACCP** controls would likely enhance compliance with existing nonsafety standards; and inclusion of controls for economic fraud and decomposition would not significantly increase the costs to industry.

FDA concludes that the **HACCP** system will have to mature, and much will have to be learned, before it can be determined whether a mandatory **HACCP** program should include nonsafety matters. Because these regulations reflect a first step in terms of mandating **HACCP** , the agency is comfortable as a matter of policy that they should initiate a system that focuses on **food** safety.
Additionally, the statutory provisions that form the basis for these regulations are safety provisions. FDA's application of **HACCP** is intended for the effective enforcement of sections 402(a) (1) and (a)(4) of...

... is whether the final regulations should retain the recommendations with regard to the application of **HACCP** to nonsafety matters.

FDA is persuaded by the comments that the proposed recommendations for **HACCP** controls of nonsafety matters, coupled with the presence of proposed Appendix D of part 123...

... often confused with or misapplied as requirements. Given this fact and the emerging nature of **HACCP** , FDA has decided to eliminate proposed Sec. 123.6(c) and Appendix D of part...

... however, because the Guide is understood as being the repository for recommendations relating to seafood **HACCP** .

The agency's decision to eliminate reference to nonsafety hazards from these regulations notwithstanding, such hazards as economic adulteration, decomposition not normally associated with human illness, general unfitness for **food** , and misbranding constitute violations of the act and are subject to regulatory action by FDA...
...will take enforcement action as it deems appropriate. Processors who are able to accommodate a **HACCP** system that covers both safety and nonsafety hazards may find advantage in doing so, in...

...proposed to provide that: Failure of a processor or importer to have and implement an **HACCP** plan that complies with this section or to operate in accordance with the requirements of...

... is injurious to health. FDA tentatively determined that such minimum requirements include the establishment of **HACCP** preventive controls. The preamble further explained that section 402(a)(4) of the act, among other things, deems a **food** to be adulterated if it is prepared, packed, or held under insanitary conditions whereby it...

...regulations do not automatically constitute adulteration. They contended that, because FDA will not be preapproving **HACCP** plans, a negative finding on the first FDA inspection could, under the language that was...

...6(g), which sets out this language, is not to create a legal presumption that **food** is adulterated if there is not perfect adherence to these regulations but to make clear...
... to ensuring the safety of seafood that if there is not adherence to them, the **food** cannot be considered to have been produced in accordance with section 402(a)(4) of...

...the potential for harm that exists.

The agency's primary concern is that processors develop **HACCP** plans that address the hazards that are reasonably likely to occur. When deficiencies in **HACCP** plans are detected during FDA inspections, the agency usually will first attempt to seek voluntary...

... that FDA will elect to pursue regulatory action. It must be noted, however, that, where **HACCP** plan deficiencies result in significant potential for consumer harm, the agency will evaluate the need...

... action with respect to the product that has been produced as well as to the **HACCP** plan itself.

In this regard, FDA notes that a change from "shall" to "may" in... indicate that when a violation occurs, FDA will evaluate the processors overall implementation of its **HACCP** plan in deciding how best to remedy the violation.

Consistent with the revisions to the...

... the "Imported Products" section of this preamble, the proposed requirement that an importer develop a **HACCP** plan (Sec. 123.11) has been eliminated in favor of a requirement for importer verification...

...importers.

Consistent with the revision to Sec. 123.6(a) and (b) that processors have **HACCP** plans only when a hazard analysis reveals one or more **food** safety hazards that are reasonably likely to occur, Sec. 123.6(g) has been amended to state that a processor's failure to have a **HACCP** plan shall render the fish or fishery products adulterated only when a **HACCP** plan is necessary.

F. Corrective Actions

The fifth **HACCP** principle, as articulated by the NACMCF, is that processors establish the corrective actions that they...

...expectation is that these corrective actions should be predetermined and written into the processor's **HACCP** plan.

In the proposed regulations, FDA tentatively chose to incorporate the principle of corrective action without requiring predetermined corrective action plans in the processor's **HACCP** plan. Instead, FDA proposed minimum, generic corrective action procedures for processors to follow. In so doing, FDA was trying to minimize the burden of the mandatory requirements of **HACCP** , especially for small processors. FDA tentatively concluded that the procedures set out in proposed Sec...

... approach as opposed to requiring that predetermined corrective action

plans be made part of the **HACCP** plan. A large number of comments responded to that request. Additional comments addressed the specifics...

... action plans. Many of those that supported mandatory corrective action plans urged consistency with the **HACCP** recommendations of the NACMCF. These comments noted that the NACMCF recommendations are consistent with Codex...

... with such international standards would minimize confusion for processors and importers, smooth international adoption of **HACCP** principles, and facilitate trade. The comments stressed that predetermining corrective action is an essential component of a processor's **HACCP** program, with the seven principles being so closely intertwined that overall success is probable only...

... from a CL. For example, one comment pointed out that corrective actions written into the **HACCP** plan would eliminate the need for employees to substantiate to management the correctness of their...

... deviation. A few comments stated that, if the appropriate corrective actions are detailed in the **HACCP** plan, responses by employees to CL failures are more likely to be immediate (reducing product...

...product safety evaluations are not readily available.

One comment asserted that the strength of the **HACCP** system is that it is preventive, and that corrective action plans are fundamental in preventing ...

... corrective action plan is less preferable than having responsible and knowledgeable personnel, adequately trained in **HACCP** , available to evaluate a deviation from a CL. If such personnel are available, one comment... in fact, encourage processors to predetermine corrective actions as part of the preparation of a **HACCP** plan.

On this issue, the merits of the various approaches tend to balance. Consequently, FDA...

... processors with the option of developing their own corrective action plans as part of their **HACCP** plans or of following a generic **model** corrective action plan, provided in the regulations, should a deviation occur.

The agency accepts the...

... be mandated in order to protect the public health. Processors can build them into their **HACCP** systems if they so choose, but the public health will be protected so long as...

... outcome is assured both with specific predetermined corrective action plans and with the minimum generic **model** that FDA is requiring as an alternative. Without additional evidence from actual experience, which was not provided by the comments, FDA cannot conclude that the overall success of **HACCP** depends on whether processors have specific predetermined plans for events that might not necessarily occur...
... revised Sec. 123.7 to permit, but not to require, processors to include in their **HACCP** plans any written corrective action plans that they develop. When a deviation from a CL...

...Sec. 123.7(c). The steps in Sec. 123.7(c) constitute a minimum generic **model** for corrective actions and, as will be explained below, closely match those that were contained...

... requirement, at Sec. 123.7(c)(5), that the processor reassess the adequacy of its **HACCP** plan when a deviation occurs.
This requirement does not exist where a corrective action plan... predetermined corrective action plans at the option of the processor) adheres to the principles of **HACCP** as recommended by NACMCF (Ref. 34, pp. 199-200) and will not result in undue...

... same time, these regulations will provide the flexibility needed to accommodate the varying levels of **HACCP** sophistication within the industry. FDA is satisfied that employee indecision in responding to CL deviations...

... avoid a situation in which the processor takes a corrective action in conformance with its **HACCP** plan, but the agency later determines that the action was inadequate.

FDA agrees that these...

... must acknowledge that such a review ordinarily will not be feasible. If processors complete their **HACCP** plans, including any corrective action plans that they choose to develop, before the effective date...

... agency intends to review corrective action plans that a processor includes as part of its **HACCP** plan during routine regulatory inspections. Where the investigator finds a shortcoming in the corrective action...

...with adequate training or experience, although FDA is not tying adequate training to training in **HACCP** (see Sec. 123.10) as it did in the proposal. FDA made this change because, as comments pointed out, a 3-day course in **HACCP** would not necessarily qualify someone to make many public health determinations of this nature. The...follows.

G. Verification

1. Overview

Verification is one of the seven commonly recognized principles of **HACCP**.

In the preamble to the proposed regulations, FDA acknowledged and discussed the recommendations of the...

... Verifying that the CL's are adequate to control the hazards; (2) ensuring that the **HACCP** plan is working properly, e.g., that it is being followed, and that appropriate decisions...

... processors to adopt verification practices but did not propose to require that a processor's **HACCP** plan specify the verification procedures. Rather, the agency tentatively concluded that verification of a **HACCP** plan would effectively occur through: (1) Comparison of the plan to guidance documents such as...

... records by trained individuals before product distribution; (4) mandatory reassessment of the adequacy of the **HACCP** plan as a consequence of CL deviations; (5) reliance on the recommendations in FDA guidelines...

... i.e., third-party experts; (6) mandatory training; and (7) investigator review of the entire **HACCP** system during routine agency inspections. FDA requested comment on whether this approach is adequate to...

... this request. Approximately one-third of these comments stated that FDA's proposed approach to **HACCP** verification was adequate. The other comments argued that verification should be specifically mandated as a part of a firm's **HACCP** program.

A few of the comments favoring the proposed approach contended that a **HACCP** plan lacking verification procedures should not be grounds for FDA to consider a product to...

...processors will engage in verification activities without a requirement, as a natural outgrowth of a **HACCP** program, because without such activities, **HACCP** will not work. For this reason, they argued, it is not necessary to mandate that verification procedures be included in processor's **HACCP** plans.

Of the comments that supported the need for specifically-mandated verification activities, a significant number urged the agency to adopt such a requirement to be consistent with the **HACCP** recommendations of the NACMCF.

These comments noted that the NACMCF recommendations are consistent with Codex...

... with such international standards would minimize confusion for processors and importers, smooth international adoption of **HACCP** principles, and facilitate trade. The comments stressed that verification is an essential component of a processor's **HACCP** program, and that the seven principles are so closely intertwined that overall success is probable...

... of the comments stated that verification should involve a continual review and improvement of the **HACCP** system. The comment added that verification is a primary responsibility of processors, one that is equivalent in importance to plan development. Several comments stated that the benefits of **HACCP** verification include: Assurance that all CCP's are identified, assurance that the plan is being...

... party oversight of the plan development process, a means of measuring the success of a **HACCP** system, and information on trends in the frequency and reasons for CL deviations. One comment...

... activities, processors would rely strictly on end-product testing to evaluate the success of the **HACCP** plan, and that such an approach would diminish the effectiveness of the entire **HACCP** system. Several comments stated that **HACCP** plan verification procedures should include detailed government and industry audits and product analyses.

One comment third-party technical assistance" is not a mandatory part of the **HACCP** program and, therefore, can not be counted on as a verification procedure. It added that...

... that verification must be an ongoing procedure. The comment stated that a "review of all **HACCP** -monitoring records by trained individuals before distribution of product" is not verifiable by the agency...

...many of the comments as appropriate verification steps. For example, the proposed requirement that the **HACCP** plan adequately address the **food** safety hazards that are reasonably likely to occur (Sec. 123.6(c) in this final...

... reviewed to assess whether they indicate a problem at a CCP; and the requirement that **HACCP** - monitoring and corrective action records be reviewed before distribution of the product. FDA now realizes...

...confusion about whether FDA intended to include or exclude the principle of verification from processors' **HACCP** programs. FDA has concluded, therefore, that verification is important enough to be an explicit part...

...verification, Sec. 123.8.

Section 123.6(c)(6) requires that processors include in their **HACCP** plans a list of the verification procedures that they will use and the frequency of...

... view of the NACMCF that a processor's verification procedures should be addressed in the **HACCP** plan (Ref. 34, pp. 200-202). FDA does not expect that this requirement will be...

... the processor for two reasons. First, the requirement that verification procedures be listed in the **HACCP** plans is really only a variation of the proposal in that FDA proposed to require...

...steps that a processor determines are appropriately a part of the annual reassessment of the **HACCP** plan need not be extensive or detailed. FDA recognizes that, at least initially, much of...

...as requested by comments, and at the same time, not unduly burdensome.

3. Verifying the **HACCP** Plan

Section 123.8(a) requires that processors with **HACCP** plans verify two aspects of their **HACCP** systems: (1) That their **HACCP** plans are adequate to control **food** safety hazards that are reasonably likely to occur, and (2) that their plans are being...

...34, p. 201).

Second, Sec. 123.8(a)(1) requires that a reassessment of the **HACCP** plan occur whenever there are any changes of the type listed in these regulations that...

... FDA agrees with the NACMCF and the comments that verification of the adequacy of the **HACCP** plan should be conducted on a regular basis, even in the absence of a recognized change, to ensure that the plan continues to address all of the reasonably likely **food** safety hazards with appropriate CL's and monitoring procedures. It is essential that processors verify...

... from the NACMCF materials on the "five preliminary steps" that form the basis for the **HACCP** plan (Ref. 34, pp. 188 and 201). A ...requires that the plan reassessment be performed by an individual that has been trained in **HACCP** in accordance with Sec. 123.10.
This requirement is a logical outgrowth of the proposed requirement in Sec.
123.9 that a **HACCP** -trained individual be responsible for the initial development of, and subsequent modifications to, the **HACCP** plan. These kinds of activities require an understanding of the principles of **HACCP** and plan development as obtained through training that is at least equivalent to the course...

...10.

Section 123.8(a)(1) also requires that, where a reassessment reveals that the **HACCP** plan is inadequate, the processor shall immediately modify the plan. Failure of a processor to immediately modify its **HACCP** plan after it has determined that the plan is inadequate would result in the processor ...

...annual verification will be through its own continuing determinations of whether the processor's overall **HACCP** system remains appropriate for the circumstances. These determinations will occur as a product of the...
... subject, FDA is sensitive to the comment that the absence of verification procedures from a **HACCP** plan should not, in and of itself, cause a **food** to be deemed adulterated under 402(a)(4) of the act. Nonetheless, the absence of...

...of having to react to the absence of adequate verification procedures in a processor's **HACCP** plan, in deciding whether to bring regulatory action, the agency will consider the totality of the situation, and the likelihood that it would have an adverse impact on the final **food** , as it would in considering a processor's failure to meet any specific provision.

4...

... form of "frequent reviews" (Ref. 34, p. 201). Frequent reviews relate primarily to whether the **HACCP** plan is functioning effectively on a day-to-day basis. It is important to note...

... in-process testing, as appropriate, in accordance with written procedures for these activities in the **HACCP** plan.

Section II H. of this preamble addresses the review of consumer complaints at some...

...can include the validation of computer hardware and software.
FDA proposed to require that the **HACCP** plan detail the methods of computer software validation to be used by the processor. FDA...

...in only marginally improved reliability.

The agency has worked extensively with the low-acid canned **food** industry to verify computer hardware and software that the industry is now using to operate...

... CL's, controlling the processing operations, taking corrective actions, and recordkeeping (Ref. 221).

In a **HACCP** system such as that being established for seafood by these regulations, FDA is interested in... The nature and frequency of the calibration effort should be determined at the time of **HACCP** plan development and should be included in the plan to ensure that it is regularly...

... in place of end-product testing, should be used to measure the success of the **HACCP** program, both in terms of individual firms and the national program as a whole, and...

... that end product testing is essential because no other verification mechanism provides public confidence that **HACCP** programs are actually resulting in a safer product.
Several comments stated that regular microbiological testing would help a processor determine whether there are sources of **contamination** that are not being controlled.

A few comments suggested that such testing should be performed...

... the need for and frequency of product analysis should be established as part of the **HACCP** plan development process.
One of these comments noted that the frequency of testing may fluctuate...

... stated that end-product testing is a questionable method for measuring the success of a **HACCP** system. One of these comments stated that end-product testing measures the effectiveness of the...

... small, finite portion of production and has limited value in measuring the success of the **HACCP** plan overall.

One comment stressed that finished product testing is contrary to the concept of **HACCP** , i.e., a reliance upon preventive controls at critical points throughout the system. Another comment...

... about product testing, reiterated its view that, while verification is essential to the success of **HACCP** , end-product testing has limited value for measuring the success of a **HACCP** system. Comments also noted that in-process or finished product testing should not normally be a prerequisite for lot release under a **HACCP** program.

However, FDA recognizes that many processors will find that product testing has a role to play in the verification of **HACCP** systems, and the agency wishes to encourage incorporation of testing into **HACCP** plans, where appropriate. Consequently, the regulations at Sec. 123.8(a)(2)(iii) list end...

... instruments, and the performing of any end-product or in-process testing. The review of **HACCP** records by a trained individual was included in the proposed regulations at Sec. 123.8...

...has included it in the section on verification.
Specifically, the proposed regulations provided that a **HACCP** -trained individual review the monitoring records, sanitation control records, and corrective action records before distribution...shipment underestimates the level of control attainable through the monitoring and corrective action

principles of **HACCP** .

Comments from several processors and trade associations stated that, for some processors, it would be impractical to withhold the shipment of every lot until **HACCP** records could be verified and signed. These comments noted that, with the use of today...

... end of the shift (lot). Several comments also stated that holding a product until the **HACCP** records could be reviewed could result in a product being subjected to unfavorable conditions during...

...compromise both quality and safety.

Several comments urged that processors be permitted to review the **HACCP** records at the end of the day or at the end of the shift, even...

...lot release leaves as the primary purpose for record review the periodic verification that the **HACCP** plan is appropriate and is being properly implemented. Record review needs to occur with sufficient frequency so as to ensure that any problems in the design and implementation of the **HACCP** plan are uncovered promptly and to facilitate prompt modifications. The concept is roughly that of...

...production of subsequent lots of the product.

FDA is convinced that a weekly review of **HACCP** monitoring and corrective action records would provide the industry with the necessary flexibility to handle...

...3) with one revision. As set out in the final rule, it requires that the **HACCP** -trained individual review the monitoring records of CCP's and the records that document the...

... and product testing. The frequency of these activities will be variable and dependent upon the **HACCP** plan development process.
Consequently, setting a specific review frequency for these records is not warranted. Section 123.8(a)(3)(iii) reflects this conclusion. It requires that the **HACCP** -trained individual review the calibration records within a reasonable time after the records are made...
... the proposal that there be a verification-type review by a trained individual of the **HACCP** records that are being created by the processor. In this respect, the responsibilities of the...

...Hazard Analysis

Section 123.8(c) requires that, whenever a processor does not have a **HACCP** plan because a hazard analysis has not revealed any **food** safety hazards that are reasonably likely to occur and that can be controlled through **HACCP** , the processor must reassess the hazard analysis whenever a change occurs that could reasonably affect...certain that a plan is still not needed.

FDA has concluded that, under a mandatory **HACCP** system, the principle of verification applies equally to a decision that a **HACCP** plan is not necessary as it does to a decision that the plan continues to...

... records of end-product testing be kept is consistent with the general recordkeeping principles of **HACCP** . The one exception is that FDA is not requiring records that document the review of...

... preamble, FDA is persuaded that most consumer complaints will involve matters unrelated to the mandatory **HACCP** system.

H. Consumer Complaints

1. Background

In the proposed regulations, FDA tentatively concluded that each

processor's **HACCP** system had to utilize any consumer complaints that the processor receives that allege a problem...

... that a processor's monitoring efforts include the use of consumer complaints, and that its **HACCP** plan reflect how they will be used. In a second provision, FDA proposed to require...

...CCP or to a possible CL deviation be included as part of the processor's **HACCP** records and be available for agency review and copying.

FDA's rationale for proposing these...

... that problems are occurring that are not being detected or prevented by the processor's **HACCP** controls. While the goal of a **HACCP** system is to prevent all likely hazards from occurring, no system is foolproof. The agency tentatively concluded,therefore, that each **HACCP** system should take advantage of consumer complaints as they relate to the operation of CCP...

... to be able to verify whether a processor is taking necessary steps to review its **HACCP** controls and take corrective actions as necessary in response to consumer complaints. The agency emphasized that it was referring solely to complaints relating to the operation of the **HACCP** CCP's (i.e., those that allege a problem with human **food** safety) and not to consumer complaints generally.

2. Consumer Complaints as Verification Tools

76. FDA...

... Generally speaking, the comments addressed two broad issues: Whether consumer complaints are relevant to a **HACCP** system, and if they are relevant, how they should be used. The question of whether...

... variant of the system (i.e., they believed that consumer complaints are relevant to a **HACCP** system). Some of those who voiced general support urged more comprehensive agency access to consumer...

... in place. The remaining approximately four-fifths of the comments, principally from seafood and other **food** processors and trade associations, argued that consumer complaints have no place in a **HACCP** system.

Those comments that opposed the mandatory use of consumer complaints in a **HACCP** system provided a variety of reasons. The comments argued that consumer complaints are generally: (1...

... hazards that develop during transportation, storage, and retail marketing, rather than processing, if they identify **food** safety hazards of any kind; (7) not traceable to a specific processing plant or lot...

...efforts from more productive tasks.

Several comments raised additional questions about consumer complaints as a **HACCP** verification tool. They suggested that there are better, more effective means of verifying that the **HACCP** plan is working properly. These suggestions are covered in the "Verification" section of this preamble... suggested that consumer complaints could be useful in FDA's efforts to verify that processors' **HACCP** programs are effective.

Another group of comments, from consumer advocacy organizations and a State regulatory agency, agreed that consumer complaints are an appropriate part of **HACCP** . One of the comments noted that the consumer performs the final quality control check, and...

...in that letter should be considered in any evaluation of the adequacy of the relevant **HACCP** plan. The comment further argued that consumer complaints could bring to light unidentified CCP's...

... not be possible under the proposed regulations because the agency limited consumer complaints in a **HACCP** system to those that may be related to a CL deviation at an existing CCP...

... is persuaded that consumer complaints generally will not make an effective monitoring tool in a **HACCP** system, primarily because they tend not to provide the kind of immediate, reliable feedback expected of a **HACCP** - monitoring system. FDA agrees with the comments that suggested that monitoring procedures under **HACCP** must provide the processor with immediate feedback on whether the process is under control and be scientifically sound.

FDA is not persuaded, however, that consumer complaints are irrelevant to **HACCP** systems. The agency received no comments that were able to demonstrate that outside sources of...

... The question, then, is whether consumer complaints can serve some legitimate verification purpose in a **HACCP** system.

While consumer complaints are not specifically addressed in the NACMCF **HACCP** recommendations, the verification portion of that document states, in part, that verification inspections should be...

...sources outside the processing plant can and should be considered in the verification of a **HACCP** plan. In fact, it is FDA's experience that consumer injury or illness complaints to the agency occasionally point out problems traceable to defective controls at the **food** processing facility (Ref. 207). Where information that has potential relevance to **food** safety is available to a processor as a result of its own consumer complaint system...

... entirely appropriate for the processor to consider that information in assessing the adequacy of its **HACCP** program. FDA accepts the possibility that many, if not most, consumer complaints that a processor...

... of CCP's, or reveal the existence of unidentified CCP's, as part of their **HACCP** verification procedures. The agency acknowledges that the absence of consumer complaints does not, by itself, verify the adequacy of a **HACCP** system. However, after taking into account all the concerns raised by the comments, the agency...

... FDA has modified Sec. 123.6(c)(4) to eliminate the proposal requirement that the **HACCP** plan describe how consumer complaints will be used in the monitoring of CCP's. The...

... 7) to eliminate the proposed requirement that consumer complaints be part of a processor's **HACCP** - monitoring records.

FDA has concluded that when a review of a consumer complaint reveals a... questioned whether FDA should have access to consumer complaints. Several comments argued that no other **food** industry is required to provide access to consumer complaints. A few specifically cited the absence...

... for FDA to mandate that processors utilize consumer complaints in assessing the effectiveness of their **HACCP** program, it is not necessary for the agency to have direct access to the firms...

... prepare a matrix of complaints, as is currently used in the voluntary, fee-for-service **HACCP** program being operated by NMFS.

Others in this group suggested that FDA have access only...

... complaints, regardless of their potential relationship to product safety, be included in a processor's **HACCP** records and be available for FDA review. These comments suggested that the FDA investigator should...

...processing facility.

Unquestionably, FDA has an essential role to play as a regulatory verifier of **HACCP** . As described earlier, the agency received a number of comments that raised concerns about the veracity of a mandatory **HACCP** system in the absence of adequate regulatory review. Moreover, FDA has concluded that this role cannot be carried out without the ability to review **HACCP** plans and a narrow category of processor's records (i.e., those that relate to...

... regard to consumer complaints, FDA is persuaded by the comments that, especially when used as **HACCP** verification records rather than **HACCP** - monitoring records as originally proposed, the public health benefits that may accrue from agency access...

... to monitoring records and plans, should be enough for FDA to adequately verify processor's **HACCP** systems.

FDA also accepts that the burden on processors if they had to segregate complaints all available information as they evaluate the adequacy of their **HACCP** plans and their implementation. Consumer complaints are one potential source of information, and a significant...

...signed by the operator or observer, (4) be reviewed for completeness and compliance with the **HACCP** plan and signed and dated by the reviewer, (5) be retained for specified periods of...

... professional societies, and academics. Several comments provided arguments that support the need in a mandatory **HACCP** program for records in general, and none specifically argued in opposition to that concept. Most...

... comments that supported the need for records stated that recordkeeping is a key component of **HACCP** . One processor's comment noted that **HACCP** records must be kept in good order so that problems can be easily tracked to their root cause. One comment stated that **HACCP** records facilitate an evaluation of safety conditions over time, rather than through a "snap shot" inspection. Another processor noted that **HACCP** recordkeeping is not overly burdensome, and that the proposed regulations would not require it to...

...to those that it already maintains.

1. Details and Signatures

78. FDA proposed that all **HACCP** -monitoring records (including records of process-monitoring instrument calibration), sanitation control records, and corrective action...

...and time of the activity that the record reflects."
79. FDA proposed to require that **HACCP** -monitoring records (including records of process-monitoring instrument calibration) and sanitation control records be signed...
...that it will enhance workers' sense of responsibility and pride in their participation in the **HACCP** system of preventive controls. Regarding worker liability, those that deliberately falsify records are liable whether... These comments argued that many processors have existing forms that can appropriately be used as **HACCP** records.

It is not FDA's intent in Sec. 123.9(a) to specify record...

... mandate record retention times but require processors to identify appropriate retention time requirements in their **HACCP** plans.

FDA rejects those comments that requested a reduction in the proposed mandatory record retention...

... processing vessels and remote processing sites and from a trade association requested that FDA allow **HACCP** records to be kept on the processing vessel or remote site for a period of...

... the difficulties associated with record storage on processing vessels and remote processing sites by allowing **HACCP** records to be moved from such facilities to another reasonably accessible location at the end...
...the following season (Sec. 123.9(b)(3)).
Additionally, the agency will, as proposed, allow **HACCP** records from any facility that is closed between seasonal packs to be permanently transferred to...

...hours.

84. Several comments urged FDA to provide for the use of computers to maintain **HACCP** records.

It was not the intent of the agency to preclude such records. To make...

... 85. In the preamble to the proposed regulation, FDA stated that, as a preliminary matter, **HACCP** plans and monitoring records appear to fall within the bounds of trade secret or commercial...pursuant to these laws. FDA specifically invited comment on the issue of public disclosure of **HACCP** records and on whether FDA has any discretion about the releasability of any **HACCP** records that it may eventually have in its possession. A large number of comments responded...

... comments, from processors, trade associations, professional associations, State and Federal agencies, and individuals, contended that **HACCP** records and plans are trade secrets and should under no circumstances be released to the public. Comments from several consumer advocacy groups countered that in many cases **HACCP** records and plans will not contain trade secret information or will contain only limited trade...

...that the final regulations contain controls over the agency's access to, and copying of, **HACCP** plans and records as the only guaranteed way to ensure confidentiality. The comments argued that the potential harm from exposure of **HACCP** plans and records to competitors or to the public is considerable and carries the threat...

...and damage to the integrity of a firm and its products.

Several comments contended that **HACCP** records will be trade secret because they will be process-specific and, therefore, will contain...

... the act and within the meaning of the FOIA. Other comments asked that FDA protect **HACCP** plans and records in the same way that the agency protects processing and quality control...

...111(d)(2) and 20.114)).
Several comments suggested that FDA specifically declare that: (1) **HACCP** plans and records are trade secrets; (2) section 301(j) of the act and the ...

...disclosed to the public.

One comment proposed that, if FDA felt obliged to release some **HACCP**-related information pursuant to FOIA requests, reports of regular inspections be released instead of **HACCP** plans and records, because such reports are likely to contain less sensitive information. Another comment ...

... avoid releasing proprietary information, the agency should describe or explain information that is contained in **HACCP** plans and records in general terms rather than release the records themselves. The comment asserted...

... to inform consumers about the relative safety of the product and the effectiveness of the **HACCP** system, while not divulging specific process parameters that are trade secret or confidential commercial.

Conversely, comments from consumer advocacy groups argued that, for the most part, **HACCP** plans and records are not trade secret or confidential

commercial. The comments asserted that much...

... consumer advocacy groups argued that, given the limited resources that FDA can devote to monitoring **HACCP** compliance, public access to **HACCP** records should be as broad as allowed under the law, so that consumer confidence in...

... formulates public access policy. Another comment stated that consumers are the intended beneficiaries of the **HACCP** seafood proposal and therefore should have the right to determine through record inspection whether processors are properly implementing the **HACCP** requirements. These comments urged FDA to routinely collect **HACCP** plans and records from processors to facilitate agency verification activities and public review of the effectiveness of the **HACCP** system. One comment from a consumer advocacy group asserted that Public Citizen Health Research Group ...

... 2d 1280 (D.C. Cir. 1983) narrowly defined trade secrets in such a way that **HACCP** plans and the records at issue in this rulemaking could not be considered trade secret.
Unquestionably, adoption of a mandatory **HACCP** system will place significant documentation requirements on seafood processors. As a result, they will **produce** records that reflect processing designs and equipment and certain types of day-to-day operations the view that FDA should be a collection point for **HACCP** records and plans so that they may be made publicly available. Nevertheless, the apprehension expressed...

...needs ways to be able to judge how and whether it is benefiting from a **HACCP** system. Neither the agency nor the industry can reasonably expect that the public will simply...

... considering developing standardized reports that would be completed by investigators at the conclusion of routine **HACCP** -based inspections and become part of agency files. As presently conceived, these reports would contain a summary of the status of the **HACCP** program in effect at the firm, similar to the suggestion of two of the comments...

... existing law and FOIA regulations. FDA's experience in seafood processing plants, its experience with **HACCP** , and its understanding from the cost-benefit modeling that has been done in the preparation of these regulations is that **HACCP** plans will take each processor some time and money to develop. Thus, the agency concludes that **HACCP** plans generally will meet the definition of trade secret, including the court's definition in...

... serve that purpose, but firms will still need to expend time and money to tailor **HACCP** to their individual circumstances.

Additionally, the agency has come to the conclusion, as a matter...

...plans should be protected to the extent possible in order to promote the implementation of **HACCP** across the seafood industry. FDA has concluded that the public will benefit from the protection of records because it will actually strengthen the **HACCP** system. So long as the legitimate public need to be able to evaluate the system can be met through other means, the confidentiality of **HACCP** records and plans generally will foster the industry's acceptance of **HACCP** . Even though **HACCP** may be mandatory under these regulations, in order for it to succeed, processors must be...

... that commitment. FDA concludes, therefore, that it is in the public interest to foster tailored **HACCP** plans that demonstrate understanding and thought, rather than promote the use of rote plans and...

... the comments, FDA has concluded that the final regulations should reflect the fact that the **HACCP** plans and records that do come into FDA's possession will generally meet the definition...

... acknowledges that there could be exceptions to this general rule. The nature of information in **HACCP** plans and records varies. Some of it could

be generally available processing methodology or procedures, based on generic or **model** **HACCP** plans or guidelines developed by the agency or some other public source, that is sufficiently...disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type **HACCP** plans that reflect standard industry practices.

There is precedent for describing in regulations the records that have protected status. The low-acid canned **food** regulations at Sec. 108.35(l) provide that, except under certain limited situations, filed scheduled...

... support these processes are to be treated as trade secret. These materials are analogous to **HACCP** plans, and their treatment is consistent with the agency's views relative to the protected status of **HACCP** plans. The comments that suggested that the low-acid canned foods regulations grant trade secret...
... comments suggested that the final regulations should require processors to provide access by FDA to **HACCP** records only after the submission by the agency of a written request for specific records...

...because processors are familiar and satisfied with such procedures.

FDA remains convinced that access to **HACCP** documents is essential to the agency's verification of a firm's **HACCP** system. A key feature of the **HACCP** verification process is access by government investigators to the **HACCP** plan, to monitoring records kept according to the plan, and to records of corrective actions that were taken in response to CL deviations. Examination of **HACCP** records enables an investigator to see how the processing facility or the importer operates over...

...system itself.

FDA rejects the idea of being required to request in writing access to **HACCP** plans and records. The agency is convinced that it has sufficiently limited its access to...

... and plans that are minimally necessary to adequately evaluate the adequacy of a firm's **HACCP** system. Section 123.9(c) has been modified slightly to clarify to which records FDA...

... bottled water regulations at Sec. 129.80(h), promulgated subsequent to the low-acid canned **food** regulations, do not contain a requirement for the issuance of a written request for records...

... have access. It has chosen to use the more recent regulations, bottled water, as the **model** for these regulations with respect to records access.

5. Agency Copying of Records

87. A...

... number of comments opposed the provision in the proposal that provided for FDA copying of **HACCP** plans and records, mostly because of concern about public disclosure. Several comments stated that the...

...s need to copy records.

There are two primary reasons for the agency to copy **HACCP** plans and records: (1) To facilitate expert review of such issues as the identification of appropriate hazards and CL's in **HACCP** plans and the evaluation of the adequacy of corrective actions taken in response to CL failures; and (2) to document suspected inadequacies of the **HACCP** plan or the firm's implementation of the plan for possible regulatory followup.

Limiting the in **food** safety control strategies through scientific review and dialog, where possible, is superior to reliance solely...

... if a firm disagrees with an investigator's findings with regard to the

sufficiency of **HACCP** plans and records. The agency is strongly committed to dialog whenever possible. Provision of a means by which senior reviewers at agency headquarters will have access to **HACCP** plans and records will facilitate that process.

FDA has concluded that the restrictions on copying...

... inefficient for FDA to identify a special class of investigators that are permitted to copy **HACCP** records and plans. FDA investigators are responsible for conducting inspections and investigations to enforce a...

... to an investigator for the copying of specific records. Until an investigator has evaluated a **HACCP** plan and validated the operations of the plant, it is not likely that the investigator will know with any certainty what **HACCP** records are appropriate for review. Additionally, inspections are often done in remote locations and under...

... between the investigator and particular supervisor. Certainly, FDA investigators will make every effort to obtain **HACCP** plans and records from responsible individuals of the firm and will, if necessary, explain the...

... successfully completed a training course that has been approved by FDA on the application of **HACCP** to fish and fishery products processing. FDA also proposed that the trained person or persons be responsible for, at a minimum, developing and modifying the **HACCP** plan, evaluating the adequacy of corrective actions taken in response to CL deviations, and reviewing...

... processing involved few hazards); (3) whether, assuming the regulations are adopted by FDA, training in **HACCP** received before they are effective should be "grandfathered" as fulfilling the training requirement; and (4...

...their support contended that properly trained personnel are essential to the development and effectiveness of **HACCP** controls, and that training is necessary to ensure consistency of approach.

Those few comments that expressed reservations about the overall **HACCP** training requirement generally acknowledged the need for a trained individual in the plant but opposed...

...the need for making such a provision mandatory.

The overwhelming support in the comments for **HACCP** training is indicative of the nearly universal view that training is essential to the effective implementation of a **HACCP** system. As stated in the preamble to the proposed regulations, this view is shared by the NAS based on the success of the training requirement in FDA's **HACCP** -based regulations for low-acid canned foods at part 113 (Ref. 54). The primary concern...

... training program. As mentioned above, the Alliance is a cooperative effort between Federal and State **food** regulatory agencies, academia, ... fishery products industry to provide support to the industry in meeting its needs relative to **HACCP** training, technical assistance, and research. Presently, the Alliance Steering Committee is comprised of representatives of...

... regional affiliates, the Sea Grant Colleges, the ISSC, the National Fisheries Institute, and the National **Food** Processors Association (NFPA).

The goals of the Alliance are to develop: a **HACCP** training course that will meet the requirements of these regulations, a mechanism for delivering the...

... Alliance is developing a 3-day course, divided about equally among: (1) The fundamentals of **HACCP** , based on the recommendations of the NACMCF; (2) the requirements of these regulations and the recommendations of the Guide; and (3) a practical exercise in **HACCP** plan development.

FDA is sensitive to the concerns expressed about the cost of training but

...

... or in lost productivity. As was previously mentioned, FDA is working with the Alliance to **produce** a low cost, 3-day **HACCP** -training course for the seafood industry, that is intended to meet the requirements of these...

... to reduce financial burden, especially on smaller processors. FDA acknowledges that a short course in **HACCP** has its limitations. For example, a 3-day course might not have anything important to...
... has significant job experience working with or for an individual who is well-versed in **HACCP** . In such a situation, if the processor loses the trained individual, it should be able...

... apprenticed with the trained individual without having to send the apprentice to a course in **HACCP** training, assuming, of course, that the apprenticeship has imparted a level of knowledge at least...

...comments identified organizations or individuals that they considered to be qualified to conduct or develop **HACCP** - training courses. The majority of the comments, which included remarks from processors, trade associations, and...

... this approach would result in a standardized, comprehensive training program that emphasizes the minimum acceptable **HACCP** requirements.
Other comments recommended that training programs could be conducted by NFPA or other trade...

... the cost savings that could be realized with trade association-provided training and through the **HACCP** training experience already possessed by the NFPA. One comment suggested that allowing many training programs would offer hundreds of professionals the opportunity to contribute to the development of **HACCP** . A few comments suggested that FDA publish a listing of approved training courses.

A comment...

... stated that the organization would work cooperatively with the Alliance in the development of a **HACCP** -training course, which it suggested should be Federally subsidized and ISSC endorsed.

A few comments suggested that the Alliance be permitted to develop the standard for **HACCP** training, and that the results be shared with all prospective trainers. A few additional comments urged that **HACCP** training be based on the recommendations of NACMCF, because such efforts would result in ...well defined.

FDA generally agrees with these comments. The agency does not intend to run **HACCP** -training courses for the industry. Rather, FDA must, of necessity, focus its **HACCP** training on government investigators. The agency anticipates that industry training will be conducted privately and through academia. This division of labor is based on the **model** that has worked well for the training requirement for low-acid canned foods.
FDA agrees, moreover, that there should be widespread opportunity for conducting **HACCP** training. It is not the agency's intent to specify or limit the field of...

... is confident, however, that Alliance training will provide a low cost opportunity for high quality **HACCP** training for State or local regulators as well as for processors.

Because FDA will not...

... be "at least equivalent to the standardized curriculum recognized as adequate by the U.S. **Food** and Drug Administration." FDA had proposed to require that training courses be "approved by the **Food** and Drug Administration."

3. Should Training Be "Grandfathered?"

91. A large number of comments addressed the question of whether training in **HACCP** received before the effective date of these regulations should be "grandfathered" as fulfilling the training...

...that FDA should grandfather.
Approximately half of these comments requested that those trained under NMFS' **HACCP** training program be grandfathered. Those that provided reasons referenced the large number that had been...

... that NMFS' training was more comprehensive than that which would be necessary under FDA's **HACCP** approach, especially because the NMFS program covers nonsafety hazards in addition to safety hazards.

Other comments supported grandfathering **HACCP** courses conducted by NFPA, Sea Grant colleges, State regulatory agencies and those organizations sanctioned by such agencies to provide **HACCP** training, and Pacific Fisheries Services. One comment suggested that graduation from a Better Process Control...

... the requirements of these regulations. Another comment urged that any training program based on the **HACCP** principles recommended by the NACMCF should be grandfathered.

One comment suggested that, in order to...

...previously conducted training.
FDA has concluded that it is not in a position to grandfather **HACCP** training received before the issuance of these regulations. Blanket grandfathering would pose the risk of...

...unduly demanding on agency resources.

On the other hand, the agency will not presume that **HACCP** training received prior to the issuance of these regulations will have to be repeated. FDA...

... of prior training only when a processor's performance demonstrates a lack of understanding of **HACCP** principles.

Nonetheless, FDA encourages processors to update any prior training to ensure that they have...

... thorough understanding of the requirements of these regulations. It may well be that many traditional **HACCP** courses will need only minimal supplementation to accommodate them to the provisions of these regulations ...10.

The ultimate determination of the success of training is whether processors are operating effective **HACCP** systems. In the initial stages of the program, at least, FDA's primary focus will have to be on whether **HACCP** plans are adequate, and the systems are being effectively implemented. FDA's interest in the...

... of training will increase when plans and systems fail to demonstrate an adequate understanding of **HACCP** and its application to seafood.

Nonetheless, FDA can state that the Better Processing School curriculum...

... these regulations. The Better Processing School was developed to instruct acidified and low-acid canned **food** processors in how to safely process such products to control the hazard of the development...

... of parts 113 and 114. The course does not provide instruction in the principles of **HACCP** or address other hazards (e.g., histamine development) to which these products might also be...

...Course Curriculum

92. A few comments suggested that the training be divided into a basic **HACCP** core and interchangeable segments based on the portions of the industry of interest to the...

...shellfish, and smoked fish).

As mentioned previously, the Alliance course includes three segments: A basic **HACCP** core, the requirements of these regulations, and the development of a **HACCP** plan. The first two segments are applicable to the entire fish and fishery products industry...

... is widely used for a variety of purposes. The agency cannot conclude that video-based **HACCP** training will not accomplish the purposes of the training requirement. For remote site processors, video...

... the 3-day Alliance curriculum is the minimum necessary to develop an adequate understanding of **HACCP** principles and essentials of **HACCP** plan development. If the curriculum were reduced any further, processors would risk having to take more time later to implement their **HACCP** systems as a result of trial and error, and as a result, the quality of their **HACCP** programs would be jeopardized.

Nonetheless, FDA is not specifying in the regulations how long the...
... be "at least equivalent to the standardized curriculum recognized as adequate by the U.S.
Food and Drug Administration." This provision will also accommodate the use of **food** processing experts, who have received training in **HACCP** that is far more extensive than that planned by the Alliance. FDA recognizes that it...

...training provided by foreign institutions.

FDA has reassessed the need for training to accomplish the **HACCP** functions assigned to importers, especially in light of changes in the imports ...are now required to conduct verification activities but are no longer required to have full **HACCP** plans of their own unless they also meet the definition of a "processor." FDA has concluded that **HACCP** training, while desirable, is not essential to the preparation of importers' verification procedures, as specified...

... importers may be unfamiliar with the technical aspects of fish and fishery product processing and **HACCP** control procedures. Knowledge about these matters would be helpful for purposes of verification. To meet...

... overseas should be conducted by foreign institutions recognized for their expertise in seafood processing and **HACCP** control. This issue will be further discussed in the "Imports" section of this preamble.

6...

... comments supported the mandatory use of testing to assess whether an individual has successfully completed **HACCP** training. Two comments further recommended that the agency could consider the training requirement to be...

...courses.

However, testing alone does not provide the kind of exposure to the concepts of **HACCP** that is necessary to result in company understanding and commitment. The function of training is...

...to test competency. The true test will be whether processors are able to implement their **HACCP** systems. Processors will be judged as plans are reviewed, and plant operations are evaluated, during...

...to periodic renewal.

The primary purpose of the training is to teach the fundamentals of **HACCP**

These are unlikely to change over time. A comprehensive discussion of seafood hazards and controls...

... enhanced training for a first time violator whose infractions have resulted from a misunderstanding of **HACCP** principles.

Whenever an infraction occurs, the nature of the remedy that is warranted depends on...

...the "Compliance" section of this preamble for a more thorough discussion of compliance philosophy under **HACCP** and available remedies.) Ultimately, however, it will be the processor who will be responsible for correcting the deficiencies in its **HACCP** system. Part of that responsibility will be determining the most appropriate method of resolving any failure to fully understand **HACCP** principles, whether through remedial training, hiring a consultant, or taking some other step. So long...

...education as an option, however.

7. Gradations of Training

99. Several comments addressed whether the **HACCP** training requirement could be satisfied by different gradations of training, depending on the complexity or...

... product being produced. The majority of these comments supported the concept of variable levels of **HACCP** training. Most did not provide the basis of their support.
Those that did suggested that...

... variations in the level of training. Several of these comments stated that the necessity for **HACCP** education and training does not vary based on the size of a company, and that...have trained staff.

The agency agrees with the comments that suggested that the need for **HACCP** training does not vary solely by the size of the processor. An understanding of the principles of **HACCP** is essential for the successful implementation of a **HACCP** program, regardless of establishment size. The agency agrees with the assertion that, in many cases...
... and cooked, ready-to-eat products. Training will be critical to ensure the success of **HACCP** in these segments.

Although the agency expects that the complexity of **HACCP** plans will vary with the number and type of hazards associated with a processing operation, an understanding of the basic principles of **HACCP** , and how to apply those principles to the processor's operations, will remain essential. The...

... of a trained individual. Two trade associations argued that contracting for the development of a **HACCP** plan by a professional consultant could be more efficient and cost effective, especially for many...

... to hiring outside consultants in terms of fostering the appropriate corporate culture and commitment to **HACCP** , FDA recognizes the importance of ensuring the flexibility that firms, especially small businesses, may need...

... logistics of the routine functions that the agency proposed must be performed by someone with **HACCP** training (i.e., record review and deviation handling). Specifically, they argued that the proposed requirements... These comments, from individuals, processors, and trade associations, asserted that a firm should have one **HACCP** trained person capable of conducting or overseeing the routine operation of the **HACCP** program, but that this individual should not necessarily be responsible for designing a firm's **HACCP** plan or making complex scientific evaluations.

Another comment suggested that it was unrealistic to expect...

... employees whose training included the course prescribed by these

regulations, especially in the areas of **HACCP** plan development and the evaluation of CL deviations and corrective actions (i.e., making evaluations...

...a deviation is safe to ship). While FDA is convinced that a short course in **HACCP** principles is important to the success of the overall program, the agency also recognizes that such a course has its limitations.

FDA has deleted the proposed requirement that the **HACCP** -trained individual be required to evaluate CL deviations and corrective actions to allow for the...

...the assistance of experts.
The kind of expertise necessary would likely involve disciplines other than **HACCP** . Moreover, the agency agrees that it is unreasonable to expect that successful completion of a 3-day **HACCP** course alone would qualify an individual to make determinations about the safety of products involved in a CL failure. **HACCP** training in such a situation could only reasonably be expected to help ensure that appropriate corrective action measures are taken and recorded from a **HACCP** perspective. Consistent with this change, FDA has modified Sec. 123.7(c)(2) to state...

... that an appropriate corrective action was taken (i.e., one that was predetermined in the **HACCP** plan, or one that was determined by a qualified expert to be sufficient to render...

... requires that the trained individual perform certain record reviews associated with the verification principle of **HACCP** , including reviews of corrective action records (see Sec. 123.8(a)(3)(ii)).

FDA has...

... has revised Sec. 123.10(a) to clarify that when a trained individual develops an **HACCP** plan for a processor, this effort may involve adapting a **model** or generic-type plan for use by that processor. FDA received a significant number of comments on the pros and cons of **model** or generic-type **HACCP** plans. This subject is addressed in various places in the preamble, most notably in the section entitled "Other Issues." In summary, the development of **model** plans can be of great benefit to the industry, especially small businesses, so long as the **model** plans are tailored by processors to meet their individual situations and are not simply copied verbatim. The agency is convinced that, in most cases, generic or **model** plans will need to be modified to some extent to fully accommodate the specifics of...

... b) provides, in part, that the trained individual is responsible for reassessing and modifying the **HACCP** plan in accordance with corrective action procedures specified in Sec. 123.7(c)(5). This...

... b) also requires that a trained individual perform the annual reassessment of the processor's **HACCP** plan as required by Sec.
123.8(a)(1). A new feature of the regulations...performed by individuals who possess the knowledge and skills that are obtained through training in **HACCP** .

Section 123.10(c) requires that a trained individual perform certain record reviews as enumerated...

...reflected in the proposal in Sec.
123.8(b) that a trained individual review all **HACCP** records for completeness and consistency with written **HACCP** procedures.

Finally, it should be noted that the requirement in the proposed regulations that trained...

... revisions are described elsewhere in this preamble. In summary, importers are given alternatives to having **HACCP** plans and are not required to take the kinds of actions for which a trained...

... relating to seafood that FDA receives in a typical year are related to plant or **food** hygiene; and (5) inspections conducted by FDA and NMFS demonstrate that a significant portion of...

...sanitation conditions.

The MSSP, conducted by NMFS, concluded that sanitation controls could be included in **HACCP** plans without overloading **HACCP** . Moreover, the FDA/NMFS **HACCP** -based seafood pilot program included sanitation CCP's. Nonetheless, FDA tentatively concluded that monitoring and...

... conditions specified in the proposal should be permitted to occur outside of a processor's **HACCP** plan so as not to overload it. Because these sanitation controls relate to an entire...

...number of CCP's, FDA felt that they would not all fit well within an **HACCP** plan.

FDA took this prescriptive approach to sanitation to assist processors so that they would not have to figure out how, or whether, to include sanitation in their **HACCP** plans and to help them resolve the sanitation problems that the seafood industry has chronically experienced. By requiring a specific, daily sanitation regime that incorporates **HACCP** -type features (i.e., monitoring and recordkeeping) to help the processor track sanitation in its...

... the proposed approach, or whether the regulations should require that processors address sanitation in their **HACCP** plans.

More than 250 comments addressed various aspects of the proposed sanitation requirements, more comments...

... not clear, however, whether the latter comments were objecting to sanitation controls as part of **HACCP** where appropriate for safety or to any sanitation approach beyond **HACCP** . The remaining approximately 85 percent of the comments, principally from processors, trade associations, and State...

... consumer confidence; (2) effective sanitation controls are a prerequisite to the proper functioning of a **HACCP** system; and (3) sanitation controls are critical to the management of microbiological hazards in both...

... consumer and those that will be cooked, the latter because of the potential for cross- **contamination** in the kitchen. The comments suggested that a prescriptive approach to sanitation is warranted because...that including sanitation requirements in these regulations would simplify compliance for seafood processors because the **HACCP** and sanitation requirements would be in one place. One comment stated that some processors would...

... treat sanitation acknowledged that effective sanitation controls are essential to the proper functioning of a **HACCP** system. As with comments that supported the proposed approach, a few of these comments identified sanitation as a prerequisite to **HACCP** .
The comments that objected to the inclusion of any sanitation requirements in these regulations provided...

... p. 27; 204; and 205). This situation is nearly the reverse of that for red **meat** and poultry, where pathogens are likely to have originated from the raw materials before they...

...A significant body of opinion holds, moreover, that good sanitation is a necessary foundation for **HACCP** . This view was articulated in comments to this rulemaking and in the proposed rule to establish **HACCP** and other requirements for the beef and poultry industries issued by USDA (Ref. 211). USDA proposed both SOPs for sanitation as a prerequisite to a **HACCP** plan and sanitation as part of **HACCP** where critical for safety (Ref. 211, p. 6789).

FDA concludes, therefore, that these regulations cannot...

... sanitation is already mandatory for all foods. Section 402(a)(4) of the act deems **food** to be adulterated if processed under insanitary conditions. The CGMP's in part 110 articulate...

... adequately in place. The following observation about culture in the preamble to USDA's proposed **HACCP** rules for beef and poultry is applicable here as well:

* * * Identification of sanitation requirements has...A few comments challenged the proposed "impermeable" standard for gloves and outer garments that contact **food** or **food** contact surfaces, suggesting that in some instances it was impractical (e.g., filleting fish);
(4...

... These comments may have been the result of a misunderstanding of the relationship between processor **HACCP** plans and the proposed sanitation controls. While the proposed controls involved monitoring and recordkeeping, they were not proposed as part of a processor's **HACCP** system. FDA did not intend to designate them as CCP's. FDA believes that the...

... SSOP that is specifically tailored to a processing operation; (2) including sanitation controls in the **HACCP** plan where they are critical to product safety; and (3) retaining the general approach of...

...in the regulations may also have been arguing that sanitation should not be part of **HACCP** but should be controlled solely through CGMP's.

a. Inclusion of sanitation controls in **HACCP** plans.

110. There was strong support in the comments for the inclusion of sanitation controls in **HACCP** plans, particularly where the controls are necessary to protect the safety of the product. The...

... s hazard analysis may reveal the need to control certain aspects of sanitation in the **HACCP** plan, especially to control hazards involving microbiological **contamination** . One comment noted that sanitation controls are likely to be components of the **HACCP** plans of molluscan shellfish processors.

Given the strong support that sanitation controls should be included in **HACCP** plans where they are critical to safety, FDA has no objection to processors including sanitation controls in their **HACCP** plans. Consequently, these final regulations state in Sec. 123.6(f) and Sec. 123.11(d) that sanitation controls for safety may be included in **HACCP** plans.

The agency has concerns, however, as to whether including sanitation controls in a **HACCP** plan will be adequate to ensure that appropriate conditions exist in a plant. The conditions that would be addressed in the **HACCP** plan will likely be those that are most critically and directly related to product safety...

... relevant to safety, but in a less direct way, would probably not be controlled through **HACCP** . For example, following the NACMCF recommendations for hazard analysis and **HACCP** plan development would likely result in the identification of a number of equipment and hand washing controls at CCP's in the **HACCP** plan for the processing of a cooked, ready-to-eat product to minimize the risk of microbiological **contamination** but not in the identification of these same controls in the **HACCP** plan for a raw finished product that would normally be cooked before consumption. In the...

... case, however, attention to sanitation would still be important in the processing plant to prevent **contamination** of the product, given that the ultimate consumer cook may be inadequate, or that the product, once

contaminated , could be a source of cross- **contamination** to other foods.

Likewise, the potential for **contamination** of either a cooked, ready-to-eat product or a raw product as a result...
...use of pesticides on or near the product, would not likely be identified in a **HACCP** plan. All of these conditions are relevant to the safety of the product and should be addressed by processors.
It is not clear whether **HACCP** can fully succeed in plants that are not in control of general sanitation practices.

The inclusion of sanitation in **HACCP** --as desirable as it may be--will not fully resolve this problem.

b. SSOP.

111...

... the proposal preferred a SSOP, either alone or in combination with critical sanitation controls in **HACCP** . Significantly, the NACMCF was among those that made this suggestion. NMFS' comment stated that, in...

...products are produced.

An SSOP places the primary burden for identifying relevant controls on the **food** processor. To meet this burden, it will be necessary for the processor to think through...

... are monitored in accordance with Sec. 123.11(b) need not be included in the **HACCP** plan and vice versa. The purpose of these provisions is to allow processors to incorporate those sanitation controls into their **HACCP** plans that they believe are appropriately addressed through **HACCP** , without having to duplicate those controls in a separate sanitation program.

6. Monitoring and Corrective...in eight general areas:
(1) The safety of the water that comes into contact with **food** or **food** contact surfaces or is used in the manufacture of ice (Sec. 123.11(b)(1...

... washing product, equipment, and employees' hands, for transporting fish in flumes, and as an ingredient. **Contaminated** water can serve as a vehicle for **contamination** of the product, both directly and indirectly (Refs. 63; 64; 65, p. 49; 66; 67...

... from a nonpotable system under negative pressure conditions, can result in the chemical or microbiological **contamination** of the potable water system (Refs.
64; 65, pp. 50 and 51; 68; 71; and...

... do otherwise would be to subject the product to an unacceptable safety risk from the **contaminants** that may be introduced by the water.

(2) The condition and cleanliness of **food** contact surfaces, including utensils, gloves, and outer garments (Sec. 123.11(b)(2)). This control...

...10 (a)(3) through (a)(5) relating to the design, workmanship, materials, and maintenance of **food** contact surfaces; the cleaning and sanitizing of these surfaces, including the frequency of cleaning and sanitizing; the impermeability of gloves and outer garments that contact **food** ; and the maintenance of gloves and outer garments.

Utensils, equipment, aprons, gloves, outer garments, and other **food** contact surfaces can be vehicles for microbial **contamination** of both the raw and finished products. **Food** contact surfaces that contain breaks, pits, cuts, or grooves, or that are porous or corroded, may harbor pathogenic microorganisms that can migrate to the product and **contaminate** it. These kinds of surfaces are difficult to clean (Refs. 65, pp. 20, and 36-48; 72, pp. 166-167; 73; and 83). Where **food** contact surfaces are

constructed of toxic materials, the product may be directly **contaminated** (Ref. 74). Inadequately cleaned **food** contact surfaces can serve as a reservoir for pathogenic microorganisms, especially if biofilms are allowed ...

...and shielded from the action of cleaning and sanitizing compounds.

(3) The prevention of cross- **contamination** from insanitary objects to **food** , **food** packaging material, and other **food** contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product...

... a)(6), (a)(7), (a)(13), and (a)(18), relating to employee practices to prevent **contamination** , to physical separation of raw and cooked product, and to plant design to prevent **contamination** .

Employees and **food** contact surfaces can serve as vectors in the transmission of pathogenic microorganisms to the **food** . These microorganisms can be introduced to the product from outside areas, rest rooms, **contaminated** raw materials, waste or waste receptacles, floors, and other insanitary objects. In the processing of...

... s hands can serve as a vector for the transmission of pathogenic microorganisms to the **food** . Hand washing and sanitizing, when performed using suitable preparations are effective means of preventing such...

...in fecal material (Refs. 63, 64, 73, 74, 84, and 85).

(5) The protection of **food** , **food** packaging material, and **food** contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological **contaminants** (Sec. 123.11(b)(5)). This control derives from proposed Sec. 123.10(a)(9), (a)(11), and (a)(12), relating to the protection of **food** from various microbiological, chemical, and physical **contaminants** .

The use of toxic compounds (e.g., pesticides, cleaning and sanitizing agents, and lubricants) is frequently necessary in the processing environment. **Food** and **food** packaging materials should be protected or removed from areas where pesticides are used, and caustic cleaning compounds should be thoroughly removed from **food** contact surfaces before processing begins (Ref. 74). Condensate which forms on an insanitary surface and...

... 123.10(a)(10), relating to the overall handling of toxic compounds to protect against **contamination** of **food** . Improper use of toxic compounds is a frequent cause of product adulteration throughout the **food** industry. Proper labeling, storage, and use of the compounds is necessary to minimize the risk...

...Ref. 74).

(7) The control of employee health conditions that could result in the microbiological **contamination** of **food** , **food** packaging materials, and **food** contact surfaces (Sec. 123.11(a)(7)). This control derives from proposed Sec.
123.10...

...to have an illness, wound, or other affliction that could be a source of microbial **contamination** .

Employees can serve as a reservoir of diseases, such as salmonellosis, shigellosis, and hepatitis, that...

...to consumers by foods.
Additionally, open sores, boils, or infected wounds present the potential for **contamination** of the **food** with such pathogenic microorganisms as Staphylococcus aureus (Refs. 22, 74, and 84).

(8) Exclusion of pests from the **food** plant (Sec. 123.11(b)(8)). This control derives from the proposed requirements at Sec...

... processing hazard rather than a sanitation issue, and should be covered by a firm's **HACCP** plan.

FDA agrees with these comments and has not included a provision on refrigeration in... in Sec. 123.11. The controls in Sec. 123.7 apply to a processor's **HACCP** system only.

7. Records

114. FDA received approximately 20 comments that addressed the issue of...

...as is the development by a processor of an SSOP. As in the case of **HACCP** records, sanitation records require that processors engage in systematic monitoring of their own sanitation practices...

LEGAL PUBLICATIONS:
...717 SEC. 402 701 404 301 201 403 406 409 704 721 801 903 -- Federal **Food** , Drug and Cosmetic Act (Act of 6/25/38...

...Pub. Law 85-929 SEC. 4 -- Federal **Food** , Drug and Cosmetic Act, Amendment (9/6/58)
19951218

17/K/32 (Item 6 from file: 180)
DIALOG(R)File 180:Federal Register

DIALOG Accession Number: 02305527 Supplier Number: 940102220
Proposal To Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products
Volume: 59 Issue: 19 Page: 4142
CITATION NUMBER: 59 FR 4142
Date: FRIDAY, JANUARY 28, 1994

...AGENCY: **Food** and Drug Administration...

...Center for **Food** Safety and Applied Nutrition

SUMMARY: The **Food** and Drug Administration (FDA) is proposing to adopt regulations to ensure the safe processing and...

... procedures include the monitoring of selected processes in accordance with Hazard Analysis Critical Control Point (**HACCP**) principles. **HACCP** is a preventive system of hazard control that can be used by **food** processors and importers. FDA is proposing these regulations because a system of preventive controls is...

TEXT:
... with molluscan shellfish consumed raw or partially cooked is greater than for any cooked flesh **food** . However, seafood overall is as safe or safer than other flesh foods in terms of...

... made in the present system of regulatory control (Ref. 7, p. 1) and repeatedly recommended **HACCP** controls wherever appropriate. "Inspection and testing should focus on actual problems (as in **HACCP** systems)," NAS concluded (Ref.
7, p. 16).

C. The Principal Hazards

The most notable seafood...

... as a whole. The size of these subpopulations is increasing, however.

Therefore, concerns about bacterial **contamination** of seafood, particularly molluscan shellfish, are increasing.

In the United States, 4.4 percent of **botulism** outbreaks have been attributed to seafood. The predominant type of **botulism** organism in aquatic environments is the kind most readily destroyed by heat. Thus, many types of processing, if done properly, can negate the risk of **botulism** from seafood.
Nonetheless, with the trend toward greater use of modified atmosphere and vacuum packaging...

...monocytogenes, a hazardous foodborne microorganism that is ubiquitous in nature and is commonly found in **food** processing environments; Salmonella, which is not a marine organism but can **contaminate** seafood through improper handling and sanitation practices; and Staphylococcus aureus, another pathogen associated with sanitation...

... disease, particularly the Norwalk and Norwalk-like agents, which are linked to the consumption of **contaminated** raw or undercooked molluscan shellfish (Ref. 7, p. 30).

3. Natural Toxins

Problems associated with...
...transmitted to humans through the consumption of finfish that have eaten these organisms through the **food** chain (Ref. 7, p. 89). The larger, more predacious fish (groupers, snappers, barracuda, amberjack) and...with parasites are avoidable through commercial freezing of the raw fish before consumption.

5. Chemical **Contaminants**

The presence of toxic chemicals in the aquatic environment creates the potential for **contamination** of seafood products. These chemicals include pesticides; other industrial chemicals, such as polychlorinated biphenyls; heavy...

... of seafood consumed in this country. This seafood has little potential to contain most chemical **contaminants** at levels of toxicological concern (Ref.
13, p. 6). However, there are some **contaminants** that can be present at significant levels, methylmercury in certain species being perhaps the most ...

... species, especially nonmigratory bottom feeders, are generally the most exposed to a variety of chemical **contaminants** (Ref. 13, p.
6).

6. Decomposition

Finfish are generally regarded as being much more perishable...

...Factors Affecting Safety

Unlike beef and poultry, seafood is still predominately a wild-caught flesh **food** that frequently must be harvested under difficult conditions and at varying distances from processing, transport...

... complicating factor in ensuring the safety of seafood is the fact that no other flesh **food** is imported in the quantity, or from as many countries, as seafood. Imports include finished...

...handle and process seafood commercially, including importers, understand the hazards associated with this type of **food** , know which hazards are associated with the types of products with which they are involved...
... hazards from occurring through a routine system of preventive controls.

The seafood industry, indeed, the **food** industry as a whole, must be primarily responsible for the safety and quality of the **food** that it produces. The regulator's primary role should be to verify that the industry...

... There are exceptions. A few States, such as Alaska, do require processors to conform to **HACCP** as a condition of doing business (Ref. 17).) While many processors and importers have such...

...of awareness of hazards specific to their products. Most of the industry does not have **HACCP** -trained personnel, and many firms lack dedicated quality assurance personnel (Ref. 18, p. 35).

Seafood.. . hazards), it is questionable whether the current regulatory system, which was developed for the general **food** supply, is best suited for the seafood industry. The current system provides the agency with...

... based upon the regulations on current good manufacturing practice in manufacturing, packing, or holding human **food** at part 110 (21 CFR part 110). For the most part, these guidelines consist of broad statements of general applicability to all **food** processing on sanitation, facilities, equipment and utensils, processes, and controls.

HACCP -type controls are listed as one of several options available to prevent **food** **contamination** (Sec. 110.80(b)(13)(i)) but they are otherwise not integral to the guidelines...every 12 hours. Such evaluations are necessary to ensure that there will not be microbiological **contamination** of the finished pasteurized product. FDA's regulations for the processing of low acid canned **food** (parts 108 and 113 (21 CFR parts 108 and 113)) require such evaluations every 4 hours as an **HACCP** -type control, but products that need refrigeration (e.g., pasteurized products) are outside the scope...

... perform cooling water sanitizer strength checks to ensure that the pasteurized product would not be **contaminated** during this process. The presence of a sanitizer in the cooling water is important to prevent **contamination** of the product after pasteurization because during cooling, some water can be drawn into hot...

... formation of histamine. Part 110 states that all reasonable precautions should be taken to prevent **contamination** and recommends temperature control as one type of precaution. Again, end-product sampling is the...

... have been demonstrated through scientific research to be necessary to ensure that the hazard from **botulism** is adequately controlled.

These parameters are process times and temperatures and salinity levels. A number...

... botulinum, type E to the maximum extent possible are critically important.

B. Alternatives Other Than **HACCP**

Continuous visual inspection of seafood is not a viable ...nearly half-billion-dollar public outlay now required to operate this kind of system for **meat** and poultry.

Another alternative would be to direct significant additional resources toward greatly increasing the...

... statistical uncertainties associated with lot sampling make this an unreliable method for ensuring safety of **food** products * * * " (Ref. 7, p. 283). FDA has traditionally sought to minimize this type of inefficiency ...

...targeting its efforts based on its experiences, but some inefficiency is unavoidable. NAS recommended the **HACCP** system as an alternative (Ref. 7, p. 283).

C. Current Import System Is Not Well...31), but pressures to cut back funding exist at all of these levels.

IV. The **HACCP** Option

Thus, the Government must find new approaches to **food** safety that enable it to become more efficient and minimize costs wherever possible. A new...

...32, p. 502.)

The "smarter and more cost effective way" chosen by the Canadians is **HACCP** .

A. What is **HACCP** ?

HACCP is a preventive system of hazard control. Its application to **food** production was pioneered by the Pillsbury Company (Pillsbury) during that company's efforts in the early 1960's to create **food** for the U.S. space program. Pillsbury concluded that then existing quality control techniques could not provide adequate assurance that the **food** being produced was not **contaminated** . The end-product testing necessary to provide such assurance would be so extensive that little **food** would be left for space flights. According to Howard E. Bauman:

We concluded after extensive...

... establish this type of control, along with appropriate record keeping, we should be able to **produce** * * * a product we could say was safe. For all practical purposes, if this system was...

... system of controls. The system has undergone considerable analysis, refinement, and testing. FDA believes that **HACCP** concepts have matured to the point where they can be formally implemented for seafood on an industry wide basis.

HACCP consists first of an identification of the likely hazards that could be presented by a...
...USDA in conjunction with FDA at the recommendation of NAS, has developed seven widely accepted **HACCP** principles that explain this process in greater detail (Ref. 34). These **HACCP** principles follow.

1. Hazard Analysis

The first step in the establishment of an **HACCP** system for a **food** process is the identification of the hazards associated with the product. NACMCF defined a hazard as a biological, chemical, or physical property that may cause a **food** to be unsafe for consumption (Ref. 34, p. 186). The hazard analysis step should include...

... also involve the establishment of preventive measures to control them. To be addressed by the **HACCP** system, the hazards must be such, according to NACMCF, that their prevention, elimination, or reduction to acceptable levels is essential to the production of a safe **food** . Even factors beyond the immediate control of the processor, such as how the **food** will be distributed and how it will be consumed, must be considered because these factors...

... risk and that are not likely to occur need not be considered for purposes of **HACCP** .

NACMCF has developed numerous issues to be considered during hazard analysis. These issues relate to...

... processors and importers to become familiar with these issues. They include, for example, whether a **food** contains any sensitive ingredients that may present microbiological hazards, chemical hazards, or physical hazards; whether sanitation practices can affect the safety of the **food**

that is being processed; and whether the finished **food** will be heated by the consumer. For seafood, this analysis is particularly important because it...

... by the NACMCF, include cooking, chilling, specific sanitation procedures, product formulation control, prevention of cross **contamination** , and certain aspects of employee and environmental hygiene. For example, a cooking step that must...

... observations or measurements to assess whether a critical control point is under control and to **produce** an accurate record for future use in verification. NACMCF identifies three main purposes for monitoring...
... must be taken; and (3) it provides written documentation for use in verification of the **HACCP** plan.

As NACMCF points out, continuous monitoring is possible with many types of physical and...

... To Be Taken When Monitoring Shows That a Critical Limit Has Been Exceeded

While the **HACCP** system is intended to prevent deviations in a planned process from occurring, perfection is rarely...

... must be a corrective action plan in place to: (1) Determine the disposition of any **food** that was produced when a deviation was occurring; (2) fix or correct the cause of...

...and (3) maintain records of corrective actions.

6. Establish Effective Recordkeeping Systems That Document the **HACCP** System
This principle requires the preparation and maintenance of a written **HACCP** plan that sets out the hazards, critical control points, and critical limits identified by the...

...records generated during the operation of the plan.

Ultimately, it is the recordkeeping associated with **HACCP** procedures that makes the system work, both from the standpoint of the **HACCP** operator (industry) and the regulator. One conclusion in a study of **HACCP** performed by the Department of Commerce is that correcting problems without recordkeeping almost guarantees that...

...preventive monitoring is occurring in a systematic way.

7. Establish Procedures to Verify That the **HACCP** System Is Working

This process involves: (1) Verifying that the critical limits are adequate to control the hazards; (2) ensuring that the **HACCP** plan is working properly, e.g., that it is being followed, and that appropriate decisions ...
... to conditions and processes in the plant. Government regulatory activities also help ensure that the **HACCP** system is working.

B. Specific Applications to Seafood

As NAS has pointed out, most health...

...of Commerce, the Environmental Protection Agency (EPA), and others. This research is designed both to **produce** information that will provide a better understanding of the toxins, bacteria, chemical **contaminants** , and other phenomena and to provide a basis for developing more advanced types of controls...

... them. Within the limits of existing scientific knowledge, however, the

industry can and should use **HACCP** to control the source and condition of raw materials based on an understanding of the likely hazards that need to be prevented.

The Pillsbury team that first applied **HACCP** to **food** production began with a systematic review of raw materials to ensure that they were not...
... development of a familiarity with the raw materials that was not a normal process in **food** product development * * *. The areas of concern ranged from the potential presence of pathogens, heavy metals...being found.

Ciguatera has been associated with recreational fishing. Processors and importers should address through **HACCP** any safety considerations that might exist with the commercial sale of recreational catch generally, depending upon species and locale.

For viruses from molluscan shellfish to be controlled, **HACCP** measures must be in place to ensure that molluscan shellfish harvested from polluted waters are...

...are not followed.

FDA is considering whether to develop good handling practice requirements (not necessarily **HACCP**) specific to fishing vessels and invites comment on this matter. FDA has traditionally refrained from...

...forming species, or any other specific component of the fleet, should be subject to mandatory **HACCP** controls.

Meanwhile, processors and importers of scombrotoxin-forming species can exercise **HACCP** controls aimed at ensuring that their incoming raw materials or imported shipments have not been time/temperature abused. Because any **HACCP** plans for such processors or importers would be clearly inadequate if scombrotoxin were not identified...

... should consider placing time/temperature requirements on vessel owners as a prerequisite to doing business.

HACCP can also be applied to control of hazards from chemical **contaminants** , even though the full range of possible chemical hazards is still imperfectly understood. Government and...

...public health advisories.

These are but a few examples of environmentally related hazards to which **HACCP** can be applied. **HACCP** controls can also ensure that hazards are not being created inside a processing facility through...

... would become more efficient and would be likely to have a much greater impact if **HACCP** controls were in place. A key feature of an inspection system tied to implementation of **HACCP** is access by Government investigators to the **HACCP** plan and to monitoring records kept under that plan. In contrast to the "snapshot" provided by current inspections, examination of **HACCP** records will enable an investigator to see how the processing facility or the importer operates...

...or regulatory action regardless of whether the processor's or importer's product is actually **contaminated** or unsafe.

HACCP is not a zero risk system, however. Problems in **food** production and processing will still occur. **HACCP** systems are designed to detect and document those problems, so that they can be corrected...

... basis of the mere occurrence of processing problems. It would be warranted, though, if the **HACCP** system is not functioning properly to detect and correct the problems, or if adulterated **food** is allowed to enter into commerce.

An inspection program tied to mandatory industry adoption of the **HACCP**

system would not be industry self-certification, nor would it be deregulatory. An investigator under such a program would perform **HACCP** reviews but not to the exclusion of other inspection activities. Thus, it is highly doubtful...

... would involve continuous or high-frequency inspection and commensurate costs, an inspection system tied to **HACCP** would not necessarily require an increase over current inspection frequencies. Recordkeeping and record inspection will...them to the extent possible, and work with the agency to integrate them into a **HACCP** - based, Federal/State network. Such an approach would be consistent with recommendations relating to the...

... especially invites comment on how the proposed FDA program should mesh with an existing State **HACCP** program for seafood, such as the program that exists in Alaska, so that inconsistent Federal and State **HACCP** requirements are not imposed.

V. The Proposal

A. Decision To Propose To Make Use of **HACCP** Mandatory

For the foregoing reasons, FDA has tentatively concluded that a new system of regulatory controls for seafood is necessary, and that **HACCP** is the appropriate system. Therefore, FDA is proposing to add part 123 to establish procedures...

... procedures under sections 402(a)(1), 402(a)(4), and 701(a) of the Federal **Food** , Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(1), 342(a...

...Act) (42 U.S.C. 264). Section 402(a)(1) of the act states that **food** is adulterated if it bears or contains any poisonous or deleterious substance that may render...

... of the act was included in the act to provide additional control over insanitary and **contaminated** foods. (H.R. Rept. No. 2139, 75th Cong., 3d sess. 6 (1938).) Section 701(a...

... result in a product that is injurious to health. These requirements include the establishment of **HACCP** preventive controls that take into account the unique characteristics of seafood products. If a processor or an importer fails to adopt and implement an **HACCP** plan that complies with the requirements that FDA is proposing, or otherwise fails to operate in accordance with these proposed provisions, it will be preparing, packing, or holding the **food** under insanitary conditions under which the **food** may be rendered injurious to health. Thus the **food** will be adulterated under section 402(a)(4) of the act and subject to regulatory...

...123.6(d).

FDA's tentative decision to adopt regulations that require the implementation of **HACCP** principles by the seafood industry is grounded in the statutory objective of preventing **food** safety and sanitation problems.

Section 402(a)(4) of the act does not require that FDA demonstrate that **food** is actually hazardous or **contaminated** in order to deem the **food** adulterated and to exclude it from commerce. Instead, under section 402(a)(4) of the act, **food** producers must assure that the **food** is not "prepared, packed, or held under insanitary conditions whereby it may have been **contaminated** with filth, or whereby it may have been rendered injurious to health." (emphasis added.)

In...

... case-by-case basis whether the conditions under which a company is processing or handling **food** satisfy section 402(a)(4) of the act.

This proposed regulation would codify an appropriate...

... emerging technical state- of-the-art and explains why FDA's initial

focus in implementing **HACCP** is on seafood. Proof that any particular process or set of manufacturing conditions in the...

... this rule is supported by several additional factors. First, as stated above, the application of **HACCP** to the seafood industry has been the subject of a substantial amount of work, by the Federal government, some States, academia, and the seafood industry itself, to develop specific **HACCP** models and otherwise to apply **HACCP** to seafood processing and importation. The **Model** Seafood Surveillance Project (MSSP) was conducted by NOAA at the request of Congress in 1986 to design an inspection system for seafood consistent with **HACCP** principles. This project resulted in the development of 16 regulatory models for specific seafood products that describe the basis for a mandatory seafood inspection system. Each **model** applies many of the NACMCF principles described above in the context of a specific product...

... was conducted with significant industry involvement. The importance of industry participation in the development of **HACCP** systems was stressed by NAS in its 1985 study of **HACCP** (Ref. 36, pp. 13, 309, and 310).
As part of the MSSP project, 49 workshops were conducted involving 1,200 industry, State, and university participants. **HACCP** controls were considered for economic fraud and plant sanitation/hygiene as well as for safety...

... United States except for low acid canned seafood, which is already subject to a mandatory **HACCP** control and inspection system under the low acid canned **food** regulations adopted by FDA.

Low acid canned seafood products represent about 25 percent of all...

... p. 23). The regulatory system in place for them represents the first formal application of **HACCP** principles to **food** by a regulatory agency. As with this proposal, the regulations for low acid canned foods...

... and they were developed through cooperation between Government and industry.

Although the low acid canned **food** regulations apply **HACCP** concepts to two hazards only, i.e., **botulism** in canned foods and **contamination** because of poor container integrity, they are regarded as a major success and demonstrate the benefits that **HACCP** can provide. **Botulism** in canned goods has been effectively controlled under the low acid canned **food** regulations and is no longer a particular source of consumer concern. NAS recently concluded that...
...of seafood items. (Ref. 7, p. 320).

Seafood industry associations have been active in developing **HACCP** systems that their members could use. For the past several years, the New England Fisheries Development Association (NEFDA) has been assisting firms in the northeast to implement **HACCP** systems through Federal grants. NEFDA's activities include a pilot project for 15 processing firms and participation in a retail seafood **HACCP** pilot (Ref. 18, p. 26).

Academia has been active as well. For example, the Oregon...

... Control Point Applications to the Seafood Industry" (Ref. 37). This publication explains the fundamentals of **HACCP** , inventories microbial hazards of seafoods, and describes **model** **HACCP** systems for specific types of seafood processing operations.

As a result of efforts like these...

...academia, a considerable amount of literature and expertise now exist to facilitate the development of **HACCP** systems by seafood processors and importers, significantly more than for most other major segments of the **food** industry.
Given the advanced state of knowledge about the application of **HACCP** to the seafood industry, FDA is proposing to make the use of **HACCP** mandatory for the seafood industry to ensure that there is compliance with section

402(a...

...act.

Second, seafood industry representatives have been urging the Federal Government to adopt a mandatory, **HACCP** -based system for years. The National Fisheries Institute, the largest seafood industry trade association, and...

... since the late 1980's, including the bills that passed both chambers in 1990, contained **HACCP** elements. While there were different views on the merits of these legislative proposals, virtually all...

... that testified on these proposals--as well as most other witnesses--expressed support for the **HACCP** concept as it applies to seafood.
The Chairman of the Interstate Shellfish Sanitation Conference (ISSC...

... Federal agencies, and industry that considers issues relating to molluscan shellfish safety, testified that a **HACCP** -type approach is now being used for aspects of the shellfish program and endorsed **HACCP** for all seafood.

Significant elements of the seafood industry continue to press for the Federal Government to institute a **HACCP** -based program. An article in a 1992 edition of a seafood trade publication on the advantages of **HACCP** concluded: "With the seafood industry under a continuing barrage of negative press regarding the wholesomeness...

... state-of-the-art program for seafood which would be of significant benefit to consumers * * *. **HACCP** -based regulation is very feasible for the seafood industry * * *. There is no reason to wait...

... President of the Pacific Seafood Processors wrote to FDA expressing support for a mandatory seafood **HACCP** program (Ref.
39). The members of that organization process the majority of domestically harvested seafood. These requests provide further evidence of the appropriateness of this proposal.

B. Preparing for **HACCP**

FDA recognizes that this proposal involves a significant departure from current practices for most processors...

...industry in the establishment of this proposed system.
The agency's experiences under both its **HACCP** -based low acid canned **food** regulations and the **HACCP** -based pilot programs for seafood that it conducted with NOAA in 1991 demonstrate the need for cooperation and technical support between the agency and the industry in order to establish **HACCP** and to make it work.

The FDA/NOAA joint pilot programs involved the development and implementation of **HACCP** -based systems by seafood processors and **HACCP** -based inspections by the two agencies. Even though the FDA/NOAA pilots involved highly motivated seafood firms that volunteered to adopt **HACCP** , the firms found it difficult initially to identify hazards and critical control points associated with their own products and processes (Ref. 40). As both the agencies and the firms discovered, **HACCP** involved new ways of thinking and behaving that were not readily understood or implemented. A... proved to be extremely helpful.

This experience reinforces the view that regulations that impose a **HACCP** - based system are needed for the seafood industry and thus represents a third factor supporting the appropriateness of this proposal. The systematic kind of preventive thinking that **HACCP** requires is not universal, but it can be adopted. Regulations will ensure that processors and importers do so.
Significantly, once participants in the pilot programs made the transition

to **HACCP** , they were able to identify benefits from using **HACCP** to themselves and to consumers in terms of product safety and quality, as well as...

... Both Canada and the EC have implemented or are in the process of implementing mandatory **HACCP** -based seafood inspection systems (Refs. 32 and 44).

Given the significance of both international and...

... 35). This move toward harmonization, coupled with the current recommendations of the Codex Committee on **Food** Hygiene encouraging the international use of the **HACCP** system (Ref. 46), clearly argue for the adoption of this approach in the United States for seafood.
Failure by the United States to adopt a mandatory, **HACCP** -based inspection system may ultimately undermine its export success, with considerable economic consequences. For example...

... the EC, Canada, Iceland, Australia, and many other fishing nations have moved to a mandatory **HACCP** approach that could affect United States competitiveness in the major seafood markets.

The EC is...

... in terms of equivalence, it is clear that the EC is looking for a mandatory **HACCP** system along the lines proposed in this regulation. Maintaining and expanding this export market is...

... the two nations' respective inspection systems and standards have made it clear that this proposed **HACCP** regulation will significantly facilitate the process (Ref. 47). Canada has recently completed implementation of a mandatory, **HACCP** -based seafood inspection program. Because Canada is the United States' third largest export market and and implementation of **HACCP** plans. The products addressed in the guidelines involve special considerations or special hazards for which...

... of general guidance, to be published separately, for processors to use in understanding and implementing **HACCP** principles in their operations.
One of these samples is specific guidance on the processing of...

... q). Additional definitions are proposed in Sec. 123.3 that are specific to the proposed **HACCP** program for fish and fishery products.

The agency is proposing to define "certification number" in...

... to define "critical control point" for purposes of these regulations as a point in a **food** process where there is a high probability that improper control may cause, allow, or contribute to a hazard in the final **food** . This is a modification of the definition of the same term in Sec. 110.3...

... point where an improper control could cause, allow, or contribute to "filth in the final **food** or decomposition in the final **food** " as well as to a "hazard" in the final **food** . Clearly, that definition is intended to apply both to human **food** safety and to certain quality issues that would not normally cause illness. In this document... eat product by proper cooking, but the hazard could still occur if the product is **contaminated** or otherwise abused elsewhere in the distribution system or in the home. This aspect of...

...in this country.

"Fishery products" in proposed Sec. 123.3(f) are any edible human **food** product derived in whole or in part from fish, including fish that has been processed in any manner. This definition reflects the tentative conclusion of the agency to propose mandatory **HACCP** requirements at this time to control hazards associated with processing and importing seafood products intended...

... compliance with all laws affecting the importation. Importers may not

always directly handle the imported **food** , but they are responsible for the safety and wholesomeness of products they offer for entry...

...in the United States (that is, the importer of record) but also includes freight forwarders, **food** brokers, **food** jobbers, carriers, and steamship representatives. These other agents often represent the importer for legal and...

... the product. Therefore, the agency has tentatively concluded that it is inappropriate to focus the **HACCP** requirements that bear on imports on these persons if they do not have authority to...

... change daily as the result of rainfall, tides, winds, and other events that can bring **contaminants** into the area. The ultimate safety of raw molluscan shellfish is contingent on the water...40 CFR part 141. Those regulations provide limits for certain microbiological, chemical, physical, and radiological **contaminants** that can render water unsafe for human consumption.

The proposed definition is slightly different from...

... 3(m) and (n) broadly to ensure the safety of seafood through the application of **HACCP** principles throughout the seafood industry. The definition of "processor" is intended to include all seafood...

... process low acid canned foods are also included, even though they are subject to the **HACCP** controls of part 113. Those controls are targeted toward a limited number of safety hazards. These proposed regulations require that processors apply **HACCP** controls to all likely safety hazards.

Consistent with the regulations at part 113, the proposed...

... that are to be used in market or consumer tests. FDA has tentatively concluded that **HACCP** controls are needed for such products because the hazards associated with them are no different...

... the proposed definition. Fishing vessels that essentially only harvest are not covered by the proposed **HACCP** regulations. As explained earlier, FDA has traditionally refrained from directly regulating fishing vessels. The agency...

... handled. FDA invites public discussion on whether this approach is adequate, and, if not, whether **HACCP** requirements should be applied directly to transportation companies. This issue is complex, especially because it is not unusual for transporters to deliver a variety of **food** products, including seafood, to several consignees during a single shipment.

The agency has also tentatively...

... training and other forms of technical assistance to States and local governments to inspect retail **food** establishments through the agency's retail Federal/State cooperative program. A major part of that cooperative program involves the development of **model** codes, some of which have been widely adopted by State and local governments. FDA is now consolidating those **model** codes into a single, updated **food** code for the retail sector. Appropriate **HACCP** -based controls are included to address seafood hazards at retail. Consequently, FDA will continue to...

... principles in these regulations could be applied to seafood at retail and to shift to **HACCP** -type inspection systems as appropriate. Because of the high perishability of fresh seafood and the sometimes lengthy and complex **distribution chain** , these products can have relatively short shelf lives by the time they reach fresh fish counters and restaurants. In addition, seafood can be subject at retail both to cross- **contamination** because of poor handling practices and to species substitution.

Improper handling of seafood and other...

... number of reported acute health problems were likely linked to handling and preparation practices in **food** service establishments (Ref. 7, p. 27). The February, 1992 edition of Consumer Reports magazine reported...

...and issuing certification numbers to shellfish processors. FDA relies on recognized governmental public health and **food** control agencies, both domestic and foreign, to carry out these functions.

The agency is proposing... set forth requirements specific to the processing and importation of fish and fishery products.

C. **HACCP** Plans

1. Summary

FDA is proposing to require in Sec. 123.6 that commercial processors and importers of fish and fishery products develop and implement **HACCP** plans in keeping with Principle 6 of the NACMCF discussed previously. Development and implementation of an **HACCP** plan requires that processors think through the entire process flow from raw materials to finished...

...over time (proposed Sec. 123.6(b)(5)).

The recordkeeping system is the key to **HACCP** . As explained above, the records will enable the processor or importer, and ultimately the regulator ...

...than only how they are functioning at a particular moment in time. Among other things, **HACCP** records can reveal trends that might otherwise go undetected until significant problems occurred.

All of these requirements reflect the **HACCP** principles developed by NACMCF.
FDA is not proposing to require that the **HACCP** plan be signed by any official of a company, but invites comment on the merits...

...the appropriate individual to sign the plan.

2. Guidelines and Other Assistance

FDA recognizes that **HACCP** plans will vary in complexity, from those having many critical control points, such as plans...

... provided in the literature. NACMCF, for example, has recommended that, to facilitate the development of **HACCP** plans, processors should create an **HACCP** team, identify the intended use and likely consumers of the **food** , and prepare a flow diagram of the entire manufacturing process to help identify critical control points.

The agency favors simplicity and the rapid development of **HACCP** plans without undue expense. The appendices at the end of the proposed regulations are intendedif incorporated into or prepared under a **HACCP** plan, would be acceptable to the agency for the types of products mentioned. To further facilitate the development of **HACCP** plans, FDA intends to issue separate **HACCP** guidance for seafood that will provide information on hazards and appropriate controls by species and...

...12 per product.

The guidance will also contain a fill-in-the-blank type of **HACCP** plan with instructions on how to complete the plan based on information in the guidance. The agency has tentatively concluded that a plan that follows this **model** is likely to be acceptable to FDA. The agency is including samples of the guidance...

... Grant extension offices, and others have already developed work sheets

and other aids to facilitate **HACCP** planning for seafood. Industry members are encouraged to contact their trade associations and state universities ...

...such matters.

3. Effective Date

Even with these forms of assistance, however, FDA recognizes that **HACCP** plans cannot be written and implemented overnight. As has already been discussed, the **HACCP** system of controls can involve new ways of thinking and performing on a routine basis...

... concluded that this period of time is sufficient to permit the development and implementation of **HACCP** plans by the industry. FDA specifically invites comment on whether 1 year will be adequate...

... agency's objective is to provide enough time to permit processors and importers to understand **HACCP** , analyze the relevant hazards, and develop an appropriate **HACCP** plan, but also to avoid unnecessary delay.

After the proposed effective date, inspection of **HACCP** plans will occur as part of routine, mandatory plant inspections and import examinations. FDA is not proposing to require that **HACCP** plans be submitted to FDA in advance, or that preapproval by FDA be a condition of their adoption or implementation.

FDA is not requiring preapproval for two reasons. First, **HACCP** plans can only properly be judged in the context of the facility itself. Thus, while ...

... the resources to make preapproval a requirement. Given the protections that are built into the **HACCP** approach, FDA tentatively finds that preapproval is not necessary to ensure that fish and fishery...

... Sec. 123.6(a) to require that every processor and importer have and implement an **HACCP** plan that is specific both to each location where that processor engages in processing and...

... cases, a processor or importer may group the fish or fish products together in an **HACCP** plan.

5. Safety Hazards Only

FDA is proposing to require at Sec. 123.6(b)(1) that **HACCP** plans identify the human **food** safety hazards that must be controlled for each fish and fishery product being processed by a processor or importer. There exists a range of opinion on whether **HACCP** should apply solely to safety hazards, as this provision proposes to require, or whether **HACCP** should apply to other types of hazards, such as decomposition not normally associated with illness in humans. One school of thought holds that **HACCP** should apply to safety hazards only in order to keep it focused and to not ...

... bearing on the primary concern of safety. Another view holds that, for seafood at least, **HACCP** -type controls can be applied to various consumer risks without generating an excessive number of critical control points. The Codex Committee on **Food** Hygiene came to the latter conclusion (Ref. 46), as did NOAA as a result of...

... experiences during the MSSP (Ref. 35, p. 70). Partly for that reason, the FDA/NOAA **HACCP** pilot programs involved **HACCP** controls for safety and **HACCP** -type controls for other hazards as well.

For purposes of these proposed regulations, however, FDA's application of **HACCP** is intended for the efficient enforcement of section 402(a)(1) and 402(a)(4 a product injurious to health.

Consequently, FDA is proposing to require that **HACCP** plans include identification of hazards that could affect human **food** safety only. To

facilitate the production of such plans, FDA has listed in proposed Sec...

... are highly unlikely to occur in the absence of those controls. If, for example, chemical **contaminants** have never been found, or have only been found in amounts significantly below levels of...

... concern in a species from a particular location, processors and importers need not identify chemical **contaminants** as a hazard that must be controlled for that fish.

As indicated earlier in this...

...proposed Sec. 123.6(b)(1)(iv) and (b)(1)(v)) are forms of chemical **contaminants** (proposed Sec. 123.6(b)(1)(iii)) but are listed separately because they can be...

...hazard in finfish consumed raw, unless that fish is commercially frozen. Unapproved direct and indirect **food** and color additives (proposed Sec. 123.6(b)(1)(viii)) are a potential hazard with most any **food** .

6. Critical Control Points

Consistent with the **HACCP** principles identified by NACMCF, FDA is proposing to require in Sec. 123.6(b)(2...
... by the critical limits, monitoring, control procedures, and recordkeeping that are done as part of **HACCP** .

7. Critical Limits

In Sec. 123.6(b)(3), consistent with NACMCF principles, FDA is...

... established by FDA in the form of action levels, regulatory limits, and tolerances for such **contaminants** as pesticides, histamine, and other **contaminants** . FDA intends to compile all such levels in the guidance document described earlier.

Other critical...Proposed Sec. 123.6(b)(4) requires that the processor or importer identify in the **HACCP** plan the procedures that it will use to control and monitor each critical control point...

... necessary to ensure that the critical control point is in fact under control and to **produce** an accurate record of what has occurred at the critical control point (Ref. 34, p...

... is monitoring of the consumer complaints received by the processor. While the goal of an **HACCP** system is to prevent all likely hazards from occurring, no system is foolproof. Consumer complaints...

... that deviations are occurring that are not being prevented or uncovered by the processor's **HACCP** controls. FDA has tentatively concluded, therefore, that each **HACCP** system should take advantage of consumer complaints as they relate to the operation of critical...

...to verify the reliability of these instruments and devices.

9. Recordkeeping

As explained above, a **HACCP** system will not work unless records are generated during the operation of the **HACCP** plan, and these records are maintained and are available for review (see section IV.A...

...this document). Thus, FDA is requiring in proposed Sec. 123.6(b)(5) that the **HACCP** plan provide for a recordkeeping system that will document the processor's or importer's monitoring of the critical control points. Proposed Sec.
123.6(b)(5) also requires that **HACCP** records contain the actual values

obtained during monitoring, such as the actual temperatures and times...

...that it is not possible for the processor to derive the full benefits of its **HACCP** system, nor is it possible for FDA to verify the operation of the system, without...

...discern trends without actual values.

In addition, proposed Sec. 123.6(b)(5) requires that **HACCP** records include the actual consumer complaints that may have been received by the processor or...

... expeditions" through consumer complaint files. Only those consumer complaints relating to the operation of the **HACCP** critical control points need be included as **HACCP** records. FDA's interest is solely in verifying that the **HACCP** system is working as it should. The agency understands the sensitivities associated with consumer complaint...

... economic adulteration. FDA is not requiring processors and importers to include nonsafety hazards in their **HACCP** plans for reasons stated previously. However, the agency is encouraging processors and importers to apply **HACCP** principles to these nonsafety hazards, and to control them in the same manner that processors...

...proposed regulations (see Appendix D).

Despite the fact that these proposed regulations do not require **HACCP** controls for nonsafety hazards, such hazards as economic adulteration, decomposition not normally associated with human illness, general unfitness for **food** , and misbranding, constitute violations of the act and are subject to regulatory action by FDA **HACCP** principles enunciated by NACMCF (Ref. 34).
First, under proposed Sec. 123.7(a)(1), any...

... that the safety determination be made by an individual who has successfully completed training in **HACCP** principles (see proposed Sec. 123.9). FDA has tentatively concluded that this requirement is necessary...

... a)(4) and (a)(5) that the processor or importer review the process and the **HACCP** plan to determine whether the deviation reveals the need to modify the process or the...

... plan. Each modification is required to be noted, dated, and maintained as part of their **HACCP** records.

FDA is proposing to require in Sec. 123.7(b) that when a processor...

... critical limit deviation or a consumer complaint and include that documentation as part of their **HACCP** records. FDA has tentatively concluded that the processor, the importer, and FDA will benefit from...

...documentation maintained by the processor or the importer.

There is a strong view in the **HACCP** literature (see e.g., Ref. 51), which is reflected in one of NACMCF's seven...

... how they will handle deviations, and that this plan should be part of the overall **HACCP** plan. FDA believes that there is merit in this view and encourages processors and importers the success of an **HACCP** system (see section IV.A.6. of this document). In recognition of this fact, FDA is proposing to require in Sec. 123.8 that **HACCP** records contain certain necessary information; that processors review records of monitoring and related activities before...

... retain records for specific periods of time; and that FDA investigators be given access to **HACCP** records.

FDA is proposing in Sec. 123.8(a) that records involving observations or measurements...

... is to ensure that the processor or importer verifies that employees are recording data in **HACCP** records, and that deviations from critical limits are being caught before products that may have...

... trained individual to ensure that the records are reviewed by a person who understands the **HACCP** system, understands the significance of a processing deviation, and knows how to respond if a deviation occurs.

FDA is proposing in Sec. 123.8(c) to require that **HACCP** records be retained for at least 1 year after they are prepared for refrigerated products...

... some processing plants may be closed on a seasonal basis. Given the nature of the **HACCP** system, however, FDA may choose to inspect at least the records of a plant even...

...the period of closure.
FDA is proposing to require in Sec. 123.8(d) that **HACCP** plans and records be available for review and copying by authorized agency employees at reasonable times. As already discussed, the agency's access to **HACCP** records is essential to ensure that the **HACCP** system is working, and that the safety of seafood is being ensured by design. FDA...is aware that there is substantial public interest in the extent to which industry-generated **HACCP** records could or should be publicly available.
As FDA understands it, the argument in favor...

... if they become public. FDA invites comment on the general question of public disclosure of **HACCP** records and on the agency's preliminary analysis of their availability, as follows.

FDA has...

... and has access by regulation to certain processing records during inspections of low acid canned **food** processors. The agency has the right to copy and take possession of these records but...

...purposes. As a preliminary matter, FDA expects to continue that practice with regard to seafood **HACCP** records.
The public availability of those **HACCP** records that FDA would possess as a result of copying during an inspection would be...

... FDA will not divulge either trade secret or commercial confidential information. As a preliminary matter, **HACCP** plans and monitoring records appear to fall within these two categories of protected records. As...

... s possession. As discussed elsewhere in this document, FDA does not contemplate the submission of **HACCP** plans or other records to FDA under these proposed regulations. The preapproval of **HACCP** plans by FDA (and thus the submission of **HACCP** plans to FDA) is simply not practical. The agency has tentatively concluded that **HACCP** plans and monitoring records will be reviewed on site by agency investigators as part of...

...at least one individual who has successfully completed a training course on the application of **HACCP** to fish and fishery products processing. The agency has tentatively concluded that training is critical to the successful implementation of **HACCP** systems in the seafood industry. Based on experience obtained during the FDA/NOAA **HACCP** pilot programs in 1991-92, the agency believes that a significant portion of the seafood industry will be unprepared to meet the requirements of a mandatory **HACCP** program without some training. As discussed earlier, the pilot program revealed a general lack of understanding of the preventive nature of **HACCP** , including misunderstandings about how to establish critical limits, control measures, corrective actions, and recordkeeping procedures (Ref. 40).

A similar concern that the industry did not understand the application of **HACCP** principles formed the basis for the training requirements in the agency's regulations for low...

...were established to implement that requirement (Ref. 54). NAS concluded that the successful application of **HACCP** principles to low acid canned foods was substantially the result of the training requirement in...

... 309). The CGMP regulations for foods in part 110 also call for training in appropriate **food** protection principles (Sec. 110.10(c)).

The often seasonal nature, remote location, and small size...

... ensure that seafood processors and importers employ at least one person who is familiar with **HACCP** .
These regulations propose to require at Sec. 123.9 that the person or persons at...

...and assessing the need for corrective actions relative to the product in question and the **HACCP** plan itself. While it is the intent of the agency to provide as much guidance...

... possible to assist processors and importers, these activities require specialized training in the principles of **HACCP** , various aspects of **food** science, and the criteria of existing regulations ...sessions, modeled after the Better Process Control Schools currently in place for low acid canned **food** and acidified **food** manufacturers, will be provided by various public and semiprivate institutions. The uniformity of this training...

... cost through the use of a video? FDA also invites comment on whether training in **HACCP** received before these proposed regulations become effective as final regulations should be "grandfathered" as fulfilling...

... fish is high. Since 1983, several large outbreaks of human listeriosis have been linked to **contaminated** foods. Although it is a relatively rare illness, the exceptionally high mortality rate among susceptible...
... several cooked seafood products have been recalled from the market in North America because of **contamination** with L. monocytogenes (Ref. 27). Seven of nine smoked fish processing facilities recently inspected by ...

... the prevention of listeriosis and other microbiologically related foodborne illnesses. FDA's CGMP regulations for **food** in part 110 set out general principles of sanitation that should be followed in plants that manufacture, package, label, or hold human **food** . They address such matters as personal hygiene and cleanliness among workers who handle **food** , the suitability of the plant design to sanitary operations, and the cleaning of **food** -contact surfaces. FDA inspections of seafood processors apply the principles in part 110.

Nearly half...

... relating to seafood that FDA receives in a typical year are related to plant or **food** hygiene (Ref. 60).
The reasons, while not entirely clear, appear to be related to factors...

...Twenty-three percent documented handling of finished product in a manner that did not preclude **contamination** .

(13) Twenty-two percent documented employees not taking necessary precautions to avoid **food contamination** .

During fiscal years 1991-92, FDA conducted abbreviated inspections of nearly all domestic manufacturers in...to design of equipment, containers, and utensils so that they did not provide protection from **contaminants** and could not be readily cleaned and effectively sanitized.

(4) Forty-three percent of plants...

...p. 42).

FDA has tentatively concluded on the basis of all of these findings that **HACCP** -type controls for sanitation as proposed below are needed. The sanitation measures required under proposed...

... MSSP project that, for seafood at least, it is possible to include sanitation within an **HACCP** system without unduly overburdening that system with large numbers of critical control points. The FDA/NOAA **HACCP** -based seafood pilot program included critical control points for sanitation. For these regulations, however, FDA has tentatively decided to propose specific **HACCP** -type requirements for sanitation, rather than require that processors identify critical control points for sanitation in their **HACCP** plans. The proposed requirements in Sec.
123.10 potentially relate to an entire facility, not...

...402(a)(4) of the act and yet at the same time not overload the **HACCP** system. FDA invites comments on this approach.

In particular, FDA invites comment on whether sanitation...

... leave sanitation as one of the procedures that is to be identified and addressed in **HACCP** plans for the control of microbiological and physical hazards (see proposed Sec. 123.6(b...agency is proposing to require that processors ensure that water that contacts the product or **food** -contact surfaces, or that is used in the manufacture of ice, is derived from a...

... in water flumes. In addition, water is often an ingredient, as in soups and glazes. **Contaminated** water can serve as a vehicle for **contamination** of the product, both directly and indirectly (Refs.
63, 64; 65, p. 49; 66, 67, and 68, pp. 1 and 2). It can also serve as a vehicle for **contamination** as the ice in which the product is stored.
The safety and sanitary quality of...

... surface waters or water from shallow wells, may be subject to microbiological, chemical, or radiological **contamination** attributable to the source itself or to surface **contamination** at the well head or intake. Private sources are also frequently untreated or minimally treated...

...123.10(a)(2), as a means of ensuring that potable water does not become **contaminated** , the agency is proposing to require that the processor ensure that there are no cross...

... from a nonpotable system under negative pressure conditions, can result in the chemical or microbiological **contamination** of the potable water system (Refs.
64; 65, pp. 50 and 51; 68, 71, and...

... and the water source itself, i.e., the municipal or private water system, can become **contaminated** .

Cross connections can best be controlled by performing periodic inspections of the potable and nonpotable...
...proposing in Sec. 123.10(a)(3) to require that the processor ensure that all **food** -contact surfaces are designed, constructed, and maintained in a manner that minimizes the potential for chemical and microbiological **contamination** of the product. Utensils and equipment can be vehicles for microbial **contamination** of both the raw and finished products. Utensils, equipment, and other **food** -contact surfaces that are made of corrosive material or wood, or that contain breaks, pits, cuts, or grooves, may harbor pathogenic microorganisms that can migrate to the product and **contaminate** it.
These kinds of surfaces are difficult to clean, with the pores and crevices shielding...

...Refs. 65, pp. 20, 36-48; 72, pp. 166 and 167; and 73).

Additionally, where **food** -contact surfaces are constructed of toxic materials (e.g., lead shucking blocks), the product may be directly **contaminated** with the toxic material (Ref. 74). Therefore, FDA

tentatively concludes that it is necessary to...

... 123.10(a)(4), the agency is proposing to require that the processor ensure that **food** -contact surfaces are regularly cleaned and sanitized with cleaning and sanitizing preparations that are suitable... microorganisms can be entrapped, shielded from the action of sanitizers, and physically bound to the **food** -contact surface of the equipment.

An effective cleaning compound is one that will lower the...

... 123.10(a)(4)(i) to require that utensils and surfaces of equipment that contact **food** during processing be thoroughly washed at the end of the day's operations. FDA is...

... require in Sec. 123.10(a)(4)(ii) that, in those operations in which microbiological **contamination** can adversely affect the safety of the product (e.g., the processing of cooked, ready...

...benefit of cleaning, pathogenic microorganisms can be protected from the action of the sanitizer by **food** residue. Conversely, while cleaning can effectively remove product residue and a portion of the microorganisms...

...that the processor inspect the condition of the utensils and surfaces of equipment that contact **food** immediately after each cleaning and sanitizing. The purpose of the inspection is to ensure the...

... operation. Sanitizers must be of sufficient strength to be effective, while excessive sanitizer concentrations can **contaminate** the product with indirect **food** additives (21 CFR part 178) (Ref. 82).
Documentation of the condition of the equipment is...

... 5) to require that the processor ensure that gloves and outer garments that contact the **food** or **food** -contact surfaces are made of an impermeable material and are maintained in a clean and...

... clean and may serve as a reservoir for pathogenic microorganisms that can migrate to the **food** during processing, in much the same manner as previously described for processing equipment (Refs.
65...

... in a clean and sanitary condition can also house pathogens that can migrate to the **food** . Therefore, FDA tentatively finds that it is appropriate to require the measures set out in...

...proposing, the sanitary condition and impermeability of gloves and outer garments that may contact the **food** or **food** -contact surfaces be checked at least daily while processing operations are occurring. Such checking will...
... are equipped with gloves and outer garments that will not serve as a source of **contamination** to the product. It will also ensure that employees are never using personally owned gloves...

...10(a)(6), the processor must ensure that employees' hands, gloves, outer garments, utensils, and **food** -contact surfaces that come into contact with insanitary objects are thoroughly cleaned and sanitized before...

... a)(7), the processor must also ensure that employees' hands, gloves, outer garments, utensils, and **food** -contact surfaces that contact raw products are thoroughly cleaned and sanitized before they contact cooked product.

Employees and **food** -contact surfaces can serve as vectors in the transmission of filth and pathogenic microorganisms to the **food** . Filth and pathogenic microorganisms can be brought into the processing environment on the employees' hands from outside areas, restrooms, **contaminated** raw materials, waste or waste receptacles, floors, and other insanitary objects (Refs. 63, 64, 73...

...salmonella, shigella, hepatitis A, and other microorganisms that pollute

harvest waters (Ref. 7). These microorganisms **contaminate** the environment in processing plants and cannot, using reasonable methods, be completely eliminated.

Proper precautions...

... as proper hand and equipment cleaning and sanitizing, must be taken to minimize opportunities for **contamination** of the finished product (Refs. 63, 64, 73, 74, and 84). Therefore, FDA is proposing...

... a)(7) that such precautions be taken with respect to hands, gloves, garments, utensils, and **food** -contact surfaces.

The agency recognizes that not all processing activities will require hand washing and...

... employees, especially as they relate to hand washing, sanitizing practices, and the potential for cross **contamination** , be checked and recorded at least every 4 hours during processing. This monitoring will ensure...

... proposing to require single-service towels or suitable hand drying devices to ensure that microbiological **contamination** does not occur though the repeated use of the same towel by several individuals. A hot-air blower is an example of a suitable hand drying device because **contamination** from individual to individual is eliminated.

In Sec. 123.10(c)(3), the agency is...

...require at Sec. 123.10 (a)(9) and (a)(10) that the processor protect the **food** , **food** -contact surfaces, and **food** packaging materials against adulteration by chemical and physical **contaminants** . Such protection is necessary to ensure that the **food** produced by the processor is safe. The use of toxic compounds (e.g., pesticides, cleaning...

.... equipment. Improper use of these compounds is a frequent cause of product adulteration throughout the **food** industry (Ref. 74). Thus, it is necessary to ensure that **food** , **food** -contact surfaces, and **food** packaging materials are not **contaminated** by these toxic compounds. **Food** and **food** packaging material should be protected or removed from areas where pesticides are used, and caustic cleaning compounds should be thoroughly removed from **food** -contact surfaces before processing begins. Finally, as an additional protection, FDA is proposing to require...

... toxic compounds be labeled, held, and used in a manner that minimizes the risk of **contamination** of the product.

FDA is proposing to require in Sec. 123.10(c) that the processing plant be inspected daily to ensure that the **food** is protected from toxic compounds, and that this inspection be documented. This check should normally...

... Sec. 123.10(a)(11) that the processor ensure that products are not exposed to **contaminants** that may drip, drain, or be drawn into the **food** . An example of such a **contaminant** is condensate, which may form on the ceilings and equipment in a processing plant. If...

... surface and then falls on the product, it may carry with it filth and microbiological **contaminants** from that surface to the **food** (Ref. 65, pp. 24 and 25).

In Sec. 123.10(c), the agency is proposing...

... require that the processing plant be inspected daily to ensure that the potential for such **contamination** is minimized, and that this inspection be documented. This check should normally be performed during the actual operations, at a time when condensate or other such **contaminating** conditions are likely to be present. As explained above, the agency has tentatively concluded that...

... the agency is proposing to require that the processor ensure that compressed gases that contact **food** or **food** -contact surfaces of equipment are filtered or treated in such a way that the **food** is not **contaminated** with unapproved indirect **food** additives or other chemical, physical, or microbiological **contaminants** . Compressed gases can be **contaminated** with oil from the compressor, filth and microbiological **contaminants** from the air intake, and rust or other physical **contaminants** from the compression, storage, and distribution equipment. Filtration at the air intake and after compression, storage, and distribution is an effective means of reducing the risk of such **contaminants** entering the **food** (Ref. 89).

FDA is proposing to require in Sec. 123.10(c)(3) that the filtration and other equipment used to protect the **food** from such **contaminants** be inspected, and the inspection documented, with such frequency as is necessary to ensure control...processor ensure that persons with sores or illnesses that present an increased risk for product **contamination** are excluded from those areas of processing where such **contamination** is likely. Employees can serve as a reservoir of foodborne diseases, such as salmonellosis, shigellosis...

... the fecal-oral route. Additionally, open sores, boils, or infected wounds present the potential for **contamination** of the **food** with such pathogenic microorganisms as Staphylococcus aureus.
Employees with suspicious illnesses or sores can be...

... to an acceptable treatment facility, restroom floors and grounds around the processing facility can become **contaminated** with pathogens. Foot traffic over the affected areas can introduce pathogens to the processing room and cause product **contamination** . Insanitary toilet facilities can also increase the potential for **contamination** of employees' hands and, ultimately, the product (Refs. 64 and 74).

FDA is proposing to...

... processing environment (Refs. 63, 64, 73, and 84). Additionally, their feces constitutes filth which can **contaminate** the **food** . A daily inspection of the processing facility, as proposed in Sec.
123.10(c), serves...

... to require that the processor ensure that the plant is designed to minimize risk of **contamination** of the **food** . Proper construction is essential if the other sanitary measures that FDA is proposing to require ...

... is necessary to ensure that these attributes do not pose an increased potential for product **contamination** . In Sec. 123.10(c)(3), the agency is proposing to require that such controls...

... proposed Sec. 123.10(d). Such corrections are essential to the proper working of the **HACCP** system. The records that are produced are subject to the recordkeeping requirements of proposed Sec. 123.8, including being subject to inspection by FDA investigators. FDA has tentatively concluded that **HACCP** -type preventive controls, including recordkeeping, will ensure that the hazards caused by insanitation are controlled by design.
Recordkeeping is the key to an **HACCP** -type system. The agency's access to these records is essential to ensuring that the...

...to that processor's needs and circumstances.

2. Evisceration of Raw Fish
In 1988, following **botulism** outbreaks traced to consumption of kapchunka, FDA published compliance policy guide (CPG) 7108.17 for...

...only to remove the viscera but to do so in a manner that does not **contaminate** the fish flesh with viscera contents.
It is the viscera that can contain the majority...

... be discarded immediately to a segregated area, using a method that minimizes the potential for **contamination** or cross- **contamination** of utensils, equipment, raw materials, and other processed products.

Uneviscerated fish that have been smoked...

... fish are being filleted, the viscera may be cut, and its contents may spill out, **contaminating** the processed fish. As a result, the opportunity arises for C. botulinum spore outgrowth and toxin production as well as for growth of other **food** spoilage microorganisms in these types of products.

Therefore, the agency is proposing to require in...

... make up over half of the seafood consumed in this country, in sharp contrast to **meat** and poultry, which are primarily domestically produced. Many of the hazards that can affect imported...

... is concerned because this system does not promote industry responsibility and accountability the way an **HACCP** -based problem prevention system would. Given when most problems with imported seafood occur, these problems can be more efficiently controlled if the seafood is subject to **HACCP** controls before it is offered for import into this country than if the product is...

...the time that it is offered for sale.
Therefore, FDA has tentatively concluded that these **HACCP** regulations should cover imported products in the same manner, to the extent possible, that they...

... a) to require that products that are offered for import be produced under the same **HACCP** and sanitation controls that it is proposing to apply to domestically produced seafood. FDA is proposing to require that importers adopt an **HACCP** plan that includes the criteria for how they will decide to purchase and then handle...

...for each type of product imported as well as a copy of each supplier's **HACCP** plan for those products, as required in Sec.
123.11(b). Under proposed Sec. 123... the proposed requirement of Sec. 123.11(b) that importers must have on file an **HACCP** plan from each of their foreign suppliers, foreign processors who wish to offer their products...

... the United States after the implementation of this regulation will have to operate under valid **HACCP** plans and sanitation control procedures and furnish copies of those plans to the U.S. importers. The foreign processors should maintain appropriate monitoring records, as dictated by the principles of **HACCP** already discussed. These records should be kept at the foreign processors' places of business.

Importers...

... to take affirmative steps to monitor that their suppliers are in fact operating under their **HACCP** plans. Thus, under this proposal, the importer will need to take such steps as: (1...

... processors' facilities; (2) obtaining certification from foreign governments that the suppliers are operating under valid **HACCP** plans or obtain certification lot by lot; (3) visiting the facilities to inspect them on...
... importers (as reflected in proposed Sec. 123.11(e)) to require their suppliers to obtain **HACCP** training such as is required in Sec. 123.9.

Proposed Sec. 123.12 provides that...

... domestic products. FDA can ensure that domestic product is being produced in accordance with the **HACCP** plan and the sanitation controls in Sec. 123.10 through direct observation and review of...

... be prohibitively expensive. However, FDA tentatively finds that mere reliance on the existence of an **HACCP** plan is not enough, and that additional evidence of compliance must be provided. FDA tentatively...

... by inspecting, at the importers' U.S. place of business, the importers' and foreign suppliers' **HACCP** plans, sanitation procedures, and records associated with the importers' plans. If these records demonstrate that the foreign processor and the importer are operating in accordance with adequate **HACCP** plans, agency will have assurance that the **food** is not adulterated under section 402(a)(4) of the act.

FDA also intends to...
... a foreign country has an advanced seafood inspection system that provides for plans that are **HACCP** based, as provided in proposed Sec. 123.12(a)(3). The existence of such a...

...as described in Sec. 123.12(a), that the product has been produced under an **HACCP** plan and under sanitation controls that are equivalent to those required of domestic processors, the...

... require in part 123, subpart C that processors of raw molluscan shellfish include in their **HACCP** plans how they control the origin of the molluscan shellfish that they process. Proposed Sec...lot of raw molluscan shellfish meets these requirements. Under this proposal, these records will constitute **HACCP** records subject to the requirements of proposed Sec. 123.8.

The agency is also proposing...

... dry heat, for a short period of time before shucking to facilitate removal of the **meat** from the shell are still considered to be raw.

Molluscan shellfish consumed raw or partially...
...Refs. 7, p.
331; and 90, p. c-4). The positive relationship between harvesting areas **contaminated** by sewage pollution and shellfish-borne enteric disease has been demonstrated many times (Refs. 7...

...probably the most common cause of seafood-borne illness.
This virus commonly occurs in waters **contaminated** by sewage effluent (Refs.
7, p. 76; 91, 92, and 95).

Before the adoption of... injurious to health. Thus, they are unfit for consumption and must be removed from the **food** supply.

FDA recognizes that all shellfish-producing States have laws that require the tagging of...

... no assurance that untagged shellfish come from safe waters. Illegal harvesting of molluscan shellfish from **contaminated** or unclassified waters is known to occur (Ref. 7, p. 331). It is also known...

... testing cannot be used in the processing of shellfish to ensure that they are not **contaminated** with one of the myriad of possible domestic, industrial, and agricultural **contaminants** that have been found in shellfish harvesting areas. Therefore, State classification of growing waters is... FDA is proposing in Sec. 123.28(a) that each processor of shellfish have an **HACCP** plan that ensures that the molluscan shellfish that it processes come only from areas that...

...a)(1), 402(a)(4), and 701(a) of the act to ensure that the **food** does not contain any added substances that may render it injurious to health and is in the **HACCP** plans of most processors of cooked, ready-to-eat products. The guideline also addresses ways...

... that FDA has suggested in proposed Sec. 123.6(c) should be covered by the **HACCP** plan. These hazards will also be covered in the separately published guidance. Economic adulteration, for...

... guidelines are intended to advise processors about what FDA believes will be acceptable in a **HACCP** plan. The agency acknowledges, however, that there are basic processing norms to which conscientious processors...

... and pasteurization processes are adequate to inactivate pathogens and must document this assurance in their **HACCP** records.
This approach is similar to that in the regulations for low acid canned foods...

... know that their thermal processes are adequate to destroy C. botulinum. The low acid canned **food** regulations do not specify to processors what their time/temperature parameters must be in order...

... documentation from the process authority that the process will be effective as part of their **HACCP** records, in accordance with proposed Sec.
123.8(c).

The process established by a process... data on the range of cooking processes (times and temperatures) applied to that product, will **produce** a safe product.

The same general principles also apply to the design of the cooking...

... and retain documentation that the equipment will provide the minimum process as part of their **HACCP** records in accordance with Sec. 123.8.

2. Container Integrity

The proposed guidelines advise in Appendix A, section 3. c. and d. that **HACCP** plans prepared in accordance with part 123, subpart A will normally identify finished product container sealing for pasteurized products and postpasteurizing cooling as critical control points. **Contamination** with C.
botulinum type E during the postpasteurization cooling step is a special **food** safety hazard that must be controlled for pasteurized products. Two potential causes of recontamination are poor container seams and **contaminated** cooling water. Consequently, the guidelines, at Appendix A, section 5, recommend controls that processors can...

... The presence of sanitizer in cooling water provides a control for the risk of microbiologically **contaminated** water being drawn into the can. A vacuum created by a collapse in the cooling...

... The guidelines advise, in proposed Appendix A, section 3. e., f., g., and h., that **HACCP** plans prepared in accordance with subpart A of part 123 will normally identify cooling after...

...Refs. 23, 78, and 79).
These cooling recommendations are generally consistent with those of the **Food** Safety and Inspection Service (FSIS) of USDA (Ref. 115) and the National **Food** Processors Association (NFPA) (Ref. 78). FDA invites comments on the specifics in App. A, section...practice represents an acceptable alternative.

The guideline advises, in Appendix A, section 3.i., that **HACCP** plans prepared in accordance with subpart A of part 123 will normally identify distribution as... As has been demonstrated for low acid canned foods, the chart itself provides an excellent **HACCP** record for the benefit of both processor and regulator. For this record to be meaningful...

... overemphasized. While, as has been stated earlier, plant sanitation has no real bearing on human **food** safety for many foods, the safety of cooked, ready-to-eat products can be easily...

... separate insanitary objects from cooked products. Sanitary zones can also minimize the likelihood of airborne **contamination** through proper

filtration and positive air pressure in the zone.

A sanitary zone is a...
... or enclosed systems. In most cases, it requires procedural changes to minimize the risk of **contamination** but not large-scale structural changes.
Canada has successfully incorporated the concept of sanitary zones for seafood processing as part of its **HACCP** -based inspection program (Ref. 116).

K. Guideline For Scombroid Toxin Forming Species

FDA is proposing...

...with foodborne illness include tuna, bluefish, mahi, mackerel, sardines, herring, kahawai, anchovies, and marlin.

This **HACCP** guidance is intended to maximize the use of controls to ensure proper handling of scombrotoxic...and prevention of recontamination can stop it (Refs. 9 and 117).

The guideline describes a **HACCP** system that emphasizes reliance upon accurate recordkeeping to show continuity of proper handling. Accurate knowledge...
...water temperatures of 80 deg.F to 90 deg.F in tropical waters, which can **produce** rapid decomposition.

Thus, rapid cooling of fish when they are captured is very important to...

...properly handled.
Such records on the handling of the fish should be part of an **HACCP** system and can be used in the specific **HACCP** plans of processors.

The harvester's goal should be to bring the fish to an...provides that no fish flesh that exhibits any organoleptically detectable decomposition should be used for **food** . Aside from the clear violation of 402(a)(3) of the act presented by such...

... other regulatory level or limit for histamine established by FDA will not be used for **food** . Moreover, the agency expects, as reflected in Appendix B, section 3.a.3.i., that...adulteration occurs when a consumer is misled about the worth, amount, or identity of a **food** product and, therefore, unknowingly pays for value not received. Economically deceptive practices in the representation of a **food** 's value may occur in a number of ways. Sections 402(b) and 403 of...
... the conditions and practices that result, respectively, in the economic adulteration and misbranding of a **food** . In addition, the Fair Packaging and Labeling Act, 15 U.S.C. 1451 et seq., requires that **food** packages and their labeling provide consumers with accurate information about the identity and net quantity of the contents, so that consumers can make fair value comparisons among products.

While any **food** may be subjected to economic adulteration or to misbranding, fish and fishery products present distinctive...

... value of the substitute species, section 403(a)(1) of the act states that a **food** shall be deemed to be misbranded if its labeling is false and misleading in any particular. More specifically, a **food** is misbranded under section 403(b) of the act if it is offered for sale under the name of another **food** . If the substituted fish is less valuable than the species represented on the label or section 402(b)(2) of the act, which states that a **food** shall be deemed to be adulterated if any substance has been substituted wholly or in...

... investigators not be prevented from quickly identifying the exact cause or agent responsible in the **food** , and from tracing it back to the correct source of the **food** to prevent further sale and consumption.

For example, in a seafood related incident that occurred...

... substitution caused investigators to erroneously suspect that the illnesses were caused by ciguatoxin because the **food** was identified as being red snapper, a species which could cause that illness. The **food** actually was mahi, a fish which is often associated with scombroid poisoning (Ref. 122).
Scombroid...

...species expected to form histamine, substituting limpets for abalone put consumers at risk from a **food** that they had not intended to eat. Thus, accurate identification of species is essential to...

...402(b)(4) of the act because a substance has been added to increase a **food** 's weight or to make it appear of greater value than it is.

A similar... all other seafood industry problems, except vessel handling practices (Ref. 128).

2. Recommended Adoption of **HACCP** -Based Methods

Although the agency recognizes that **HACCP** was developed primarily to address safety, FDA believes that the proposed requirement in Sec. 123.6, for seafood processors to adopt **HACCP** methods to ensure the safety of seafoods provides an opportunity for processors to develop and...

... 7108.23). Consequently, the agency is proposing in Appendix D to establish a guideline for **HACCP** -based procedures to avoid economic adulteration and misbranding of seafoods. Following this guideline will enable...

... material receipt, processing, and labels and labeling that processors and importers can incorporate in their **HACCP** plans. The agency believes that proper control begins with verification of the raw materials received ...

... in Appendix D, section 2.a., the agency is suggesting that, as part of their **HACCP** plan, processors and importers should include critical control points beginning with the receipt of raw...of crab flavored surimi cannot be used in whole or in part instead of crab **meat** in a product labeled as crab cake.
Under Appendix D, section 2.b.4., the...

...Including Specific Guidance on Smoked Fishery Products

As an adjunct to its rulemaking to require **HACCP** procedures in the seafood industry, FDA is drafting an extensive guidance for processors to use in understanding and implementing **HACCP** principles for their operations. This guidance will provide information that processors and importers can use in the development of their **HACCP** plans. This information consists largely of an identification of hazards that can affect the safety...

...least minimize the likelihood of their occurrence.

FDA has included selected portions of the draft **HACCP** guidance as Appendix 1 to this proposal, so as to better inform the public about...

... about the kinds of assistance that will be available to processors and importers who implement **HACCP** . The agency emphasizes, however, that this guidance is a work-in-progress and still being...

...specific guidance on time- temperature and salinity parameters and other matters for use in the **HACCP** plans of processors of smoked and smoke-flavored fishery products. While FDA is seeking comment...

... processing of smoked and smoke-flavored fishery products is found in various sections of the **HACCP** guidance because this general guidance is

primarily organized by hazard rather than by commodity type...

...them into any final regulation that results from this rulemaking.

While no known outbreaks of **botulism** attributed to smoked fish have been reported since 1963, FDA believes that the failure by...

... of packaging provide an anaerobic environment in which C. botulinum spores can grow out and **produce** botulin, the causative agent in **botulism** . When consumed, the toxin attacks the central nervous system and may cause death if untreated...

... The concentration of C. botulinum spores that may be expected in and on a naturally **contaminated** fish is unknown, although it is reported to vary ...one spore per 200 g (Refs. 153 and 180).

Under certain conditions, C. botulinum can **produce** a toxin that causes **botulism** , a disease that attacks the central nervous system of humans and can cause death within...

... Since 1983, several large outbreaks of human listeriosis have been linked to the consumption of **contaminated** foods (Refs. 130, 131, and 132), thereby demonstrating the etiologic importance of foodborne transmission of...

... several cooked seafood products have been recalled from the market in North America because of **contamination** with L. monocytogenes, but these crises did not involve smoked or smoke-flavored fish products...

...and smoked fish products in Iceland has shown that 29 percent of samples tested were **contaminated** with Listeria species, including L. monocytogenes (Ref. 141). Another survey revealed that 8.9 percent and 13.6 percent of hot- and cold-smoked fish, respectively, were **contaminated** with L. monocytogenes (Ref. 142). Cold-smoked fish may pose a significant health risk, particularly...

... In contrast, studies have shown that properly controlled hot-smoking processes effectively eliminate L. monocytogenes **contamination** (Ref. 144). In raw trout inoculated with high doses of L. monocytogenes, stored for 12...

... up to 20 days of storage. These findings further emphasize the importance of preventing the **contamination** of processed fish.

Studies have also shown the importance of controlling the salt concentration in...

... use of the sanitary practices and processing practices proposed in this document should prevent cross- **contamination** and growth of the organism in smoked and smoke-flavored seafoods.

Smoking fish is a... spoilage odors that would warn consumers away from potentially dangerous products would not be present.
Botulism toxin alone is not detectable by sensory examination.

In addition, because of the number and...

... of the product relative to other seafood processing procedures. Increased handling presents increased opportunities for **contamination** during the process than would otherwise be the case.
The finished product also is inherently...

... eating. However, the present evidence indicates that smoked fish has caused no more cases of **botulism** in the United States than any other type of seafood product. In contrast, fresh fillets...

... are intended to be cooked before consumption. Cooking is lethal to bacteria and will deactivate **botulism** toxin. Thus, smoked fish products usually do not get the benefit of an additional processing...

... In 1970, FDA issued a final rule for smoked fish in response to outbreaks of **botulism** attributed to vacuum-packaged smoked fish products (35 FR 17401, November 13, 1970). Among other things, the rule attempted to control the risk of **botulism** by setting conservative processing parameters for time, temperature, and salinity that would minimize the opportunity...

... The rule was overturned in court due to procedural problems (United States v. Nova Scotia **Food** Products Corp., 568 F.2d 240 (2d Cir. 1977)). However, in rethinking this rule after...

... in 21 CFR part 110, "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human **Food** " (Ref. 196) and in the FDA Inspection Operations Manual, Chapter 5, Establishment Inspection and section...

... officials in these inspections include: (1) Live flies in production areas providing a vehicle for **contamination** and recontamination of products; (2) standing water in production rooms providing a medium for microbial growth and **contamination** from splashed water; (3) utensils not sanitized prior to use; (4) open bags of raw materials in storage areas exposing products to flying insects and potential microbial **contamination** ; (5) smoke racks encrusted with pieces of fish from previous processes, thus providing an opportunity...

... for both raw and finished products, thus providing an environment for microbial growth through cross- **contamination** between unprocessed and processed products; (7) overcrowded fish in brine tanks, whereby some fish are...

... C. botulinum spore outgrowth and toxin production; and (10) poor employee practices that foster microbial **contamination** , including spitting into sinks adjacent to sinks used to thaw product, not washing or sanitizing... of its Fiscal Year (FY) 91 Domestic Fish and Fishery Products Inspection Assignment, FDA conducted **food** safety inspections of smoked fish establishments. These inspections revealed a continuing pattern of problems in...apply to these products as a class and that will typically be identified in the **HACCP** plans of most processors of smoke and smoke-flavored products. The guidance also addresses ways...

... developed through years of research. Processors whose TTS values fall below these minimums do not **produce** a safe product and shift much of the burden of preventing **botulism** toxin outgrowth to those who take possession of these products after they leave the processing...

...refrigerators are unable to maintain this temperature (Ref. 201).

These TTS minimums are known to **produce** a marketable product, because there are processors that operate in conformance with them. Moreover, because...

... TTS values provide the only scientifically valid way developed to date of ensuring that no **botulism** toxin will be produced over the shelf life of the product under proper refrigeration conditions...

...time as proposed guidance to ensure maximum flexibility. If these values are reflected in the **HACCP** plans that are required by proposed subpart A of 21 CFR part 123, and are...

... processors to use alternative processing parameters so long as these alternatives were scientifically demonstrated to **produce** an equivalent level of safety. (Section 11 of the guidance relating to smoked and smoke ...

... the guidance relating to smoked and smoke-flavored fishery products in Appendix 1): (a) for **botulism** , zero toxin production in the product during a time period through--and slightly beyond-- the...

...the FDA Fish and Fishery Products Hazards and Controls Guide and control safety through the **HACCP** requirements for all seafood in proposed subpart A.

FDA requests comment on which of these...

... As described in section IV.A. of this document, one of the NACMCF's seven **HACCP** principles involves verification that the **HACCP** system is working.
NACMCF recommends that **HACCP** plans include procedures for verification of the **HACCP** system (Ref. 34, p. 200). FDA advises processors to consider adopting this recommendation, but has...

...firm's consistency with the controls and limits to be provided by FDA in the **HACCP** guidance described in section VII.C. and M. of this document; (2) third-party technical assistance provided through trade associations, universities and government agencies; and (3) review of all **HACCP** monitoring records by trained individuals before distribution of product (see proposed Sec. 123.8(b...

... proposed corrective action requirements (see proposed Sec. 123.7), especially the provision for assessment of **HACCP** plans as a consequence of deviations (Sec. 123.7(a)(4)); the recommended use of...

... NACMCF verification principle is being properly addressed, both for individual firms and for the overall **HACCP** program.

For individual firms, NACMCF specifically discourages ...the efficacy of end-product sampling as the only way to measure the success of **HACCP** . These caveats notwithstanding, FDA invites comment on what tests should be used to measure success...
...as a whole, and how frequently such tests should be administered.

VIII. Other Approaches to **HACCP**

This preamble has described in great detail the **HACCP** system that is being proposed and the reasoning behind each proposed provision. While the agency...

... provision, FDA also invites comment on the overall system, including whether some other approach to **HACCP** or some variation of the proposed approach might be preferable. Variations on the proposed approach include, but are not limited to: (1) Requiring **HACCP** only for higher risk seafood products; (2) exempting small firms from **HACCP** requirements; (3) staggering the effective date for implementation based on size of firm or risk...

...discussion of each of these variations follows:

A. Higher Risk Only

An alternative to requiring **HACCP** for all commercial seafood products would be to require it for products or processes that...

... in the preamble, the fact that the system is not recording illnesses from a particular **food** does not mean that illnesses are not occurring. Also, potential for harm need not always...

... terms of the number of illnesses that are actually occurring. For example, some problems, like **botulism** , may occur infrequently, but when they do, the consequences can be devastating. Based on the...

...fish, cold-process smoked and cold-process smoke- flavored fish, because of the hazards of **botulism** and listeria; (2) cooked, ready-to-eat products, because of the microbiological hazards associated with...

... be cooked by the consumer; (3) low acid canned foods, because of the hazard of **botulism** and general complexity of the processing operation;

(4) raw, ready-to-eat products, because of...

...require a judgment as to appropriate location of harvest to avoid unsafe pesticide or industrial **contaminant** levels.

FDA also invites comment on the effect of using a modified approach on the ...

... regulation. Even if exempted, these firms would still be subject to the requirements of current **food** safety law and to inspection by FDA and State authorities.

As stated earlier in this...

...how a small firm should be defined for purposes of an exemption.

The implementation of **HACCP** may be more burdensome for small firms than for large firms. Large firms tend to...

...firm. On the other hand, FDA is taking steps, such as the preparation of its **HACCP** guidance, to minimize the cost of these regulations for small businesses.
Thus, such an exemption...

... have quality control systems, an exemption for small business would appear to result in requiring **HACCP** for that segment of the industry (i.e., large firms) that needs it the least...
...small.

Nonetheless, an exemption for small business could be limited to those small businesses that **produce** low risk products, and FDA invites comment on this approach. As stated earlier, however, the...

...the exemption should be.
Should a firm be exempt from all or part of the **HACCP** requirements? As circumstances change, a **HACCP** -based analysis of risk by a firm might reveal that the firm has become a... final rule based on the comments received, the agency would still encourage voluntary adoption of **HACCP** systems by exempted firms. The advantages that **HACCP** is expected to provide in terms of consumer confidence, control of process, and access to ...

... on the effect of a small business exemption on the regulation of imports. How would **HACCP** be applied to imports under a tiered approach? Would it be possible to treat domestic...

... larger firms. As suggested earlier, large firms are probably much more able to implement a **HACCP** system than are small firms. Theoretically, the longer lead time for small firms would allow the private sector to develop an infrastructure that could help small firms implement **HACCP** . Such an infrastructure could include process authorities (see the preamble discussion on cooked, ready-to...

... later date. For example, FDA is considering whether it should make the first review of **HACCP** plans by agency investigators a nonregulatory evaluation to facilitate plan development by the processor (although...

... As has already been explained in this preamble, FDA has proposed only the basics of **HACCP** in order to keep the regulatory burden to a minimum. Several features of **HACCP** included within the NACMCF's seven principles, such as flow charts and the establishment of " **HACCP** teams," are noted in this preamble, but FDA has not proposed to require them. Nonetheless...

...industry segments.

(3) Deleting some or all of the proposed specific sanitation requirements.

(4) Requiring **HACCP** only for the domestic industry. The **HACCP** requirements would become the basis for negotiating agreements with other

countries relating to the equivalency of regulatory programs.
(5) Deleting or modifying the proposed training requirements.

(6) Requiring **HACCP** for processing hazards only. The Canadian **HACCP** system does not involve species-related safety hazards.

(7) Exempting warehouses.

(8) Although only in...

...individually.

E. Information and Consumer Awareness

In addition to requesting comment on alternative approaches to **HACCP**, FDA is taking the opportunity to invite comment on the general subject of complementary risk...

... toward postprocessing handling. Elsewhere in this document, FDA invited comment on the advisability of applying **HACCP** or alternative regulatory approaches to commercial entities that are not directly subject to these proposed... and information that should be directed toward consumers and recreational fishermen. The commercial application of **HACCP** principles can mitigate somewhat the effects of poor consumer handling practices by helping to ensure...

... the home, but no such program can prevent illnesses caused by improper home handling. Similarly, **HACCP** practiced by processors can have no effect on recreational fishermen who consume their own catch...

... consumers on the labeling of seafood. The Department of Agriculture has proposed such requirements for **meat** and poultry (58 FR 58922, November 4, 1993).

FDA has a longstanding program to control...

...products and Salmonella in all foods. These proposed regulations require control of microbial pathogens through **HACCP** principles, including specific sanitation controls. Even so, FDA recognizes that no system can reduce all...

... zero. Because all foods in the home, including seafood, are subject to mishandling and cross **contamination** from other sources, FDA invites comment on the general subject of handling instructions. Should FDA...
... propose handling instructions, it would do so as a regulatory proposal separate from the proposed **HACCP** requirements for seafood.

IX. Paperwork Reduction Act

This proposed rule contains requirements for information collections...

... points in the production and inspection of fish and fishery products as established in the **HACCP** plans of processors and importers. The specific information collected and the frequency of collection will...

... determine whether products were processed under sanitary conditions and processed, packaged, stored, and distributed using **HACCP** control techniques to avoid hazards that might cause the products to be adulterated. The information...

... products and to alert them when a deviation from the critical limits established in the **HACCP** plan has occurred that may create a potential public health hazard in the final product...

... agency has anecdotal evidence that the burden on firms that are operating under a mandatory **HACCP** system established by the State of Alaska is more nominal. Consequently, FDA acknowledges the possibility...

frequency of both snapshot inspections and sampling under the existing approach; (3) beginning a voluntary **HACCP** program in addition to the existing approach; (4) beginning mandatory **HACCP** for high risk products only, in addition to the existing approach; (5) beginning mandatory **HACCP** for all seafood (the proposed approach); (6) beginning a more comprehensive mandatory **HACCP** program than that proposed, similar to the **Model** Seafood Surveillance Project (MSSP), which would include all CGMP's, quality factors, and economic fraud as critical control points; and (7) beginning a mandatory water-to-table **HACCP** program which would include all vessels, carriers, and retail **food** operators.

The existing approach does not adequately address the compelling public interest in further ensuring...

... in the preamble to the proposed regulations and in the PRIA. The third option, voluntary **HACCP** , has been in existence at NOAA and has very few participants. The forth option, risk-based **HACCP** , has been evaluated in the PRIA in several forms, including **HACCP** only for the highest risk products from a historical perspective and **HACCP** only for those products with the potential for catastrophic risk. For example, one possibility evaluated under this option would be to implement **HACCP** solely for molluscan shellfish, which NAS and other groups have concluded constitute most of the...

... proposed option and includes more reliance on CGMP's. Finally, the last option involves mandatory **HACCP** for nearly 1 million establishments.

The options evaluated in the PRIA have both lower and...

...comment on them.

The first source is U.S. seafood processors that have actually implemented **HACCP** systems. The number of such firms may exceed 100. Understandably, many firms are reluctant to second source is a study of the costs of implementing a form of **HACCP** that was developed by the Department of Commerce for the congressionally mandated MSSP. That study...

...Costs: Actual Industry Experience

FDA has some information relevant to the actual costs of implementing **HACCP** experienced by a number of seafood firms. While this information is neither detailed nor complete...
... evaluation questionnaire from four of the eight firms that participated in the FDA/NOAA seafood **HACCP** pilot in 1990-1991 (Ref. 40). It also includes information more recently provided to FDA...

... Fisheries Development Association (NEFDA) provided FDA with summary information about member firms that were implementing **HACCP** systems. NEFDA has operated a **HACCP** pilot with member firms through a Federal grant. The two trade associations provided information on...

... to-eat products as well as molluscan shellfish. The majority of firms were involved in **HACCP** as participants in either pilot programs, the NOAA fee-for-service program, or the State...

... program, and therefore have been subject to some form of third party verification of their **HACCP** systems. Virtually all of them developed **HACCP** plans, and the majority of these included critical control points for quality or economic fraud...

...to safety.
In this respect, the majority of firms implemented a more extensive form of **HACCP** than is being proposed by FDA.
Presumably, start-up costs for **HACCP** are normally higher than operating costs in subsequent years. The majority of firms that could...

... may be firms that decided to hire additional personnel in order to install or implement **HACCP** .

It should be noted that the cost figures that come from firms that operate more...

... hire additional personnel or did not anticipate hiring additional personnel as a result of operating **HACCP** systems as those who did or felt the need to do so. The overwhelming majority of firms reported that they believed that the advantages they derived from **HACCP** were worth the costs to them in terms of better control over their operations, better...

... greater efficiencies, such as reduced waste. Virtually all foresaw long-term benefits from operating under **HACCP** .

FDA notes that there are several uncertainties with this data. The first is that FDA does not know the extent of previous **HACCP** -type activities in these firms so that they may have different incremental costs than the...
...the MSSP study sent teams into 130 processing plants, none of which were operating under **HACCP** systems, to project the costs to each plant to implement and operate a form of **HACCP** chosen for that study.

In areas where FDA had better data than that used in...

... of the first year costs can be attributed to expenditures necessary to comply with the **HACCP** -based sanitation provisions of the proposed rule. Another 36 percent are attributable to monitoring and...

...as temperature indicators, temperature recorders, and can seam tear-down machines. Additional costs are for **HACCP** training, consulting by processing authorities, writing **HACCP** plans, instituting operational changes, responding ...to these proposed regulations. Although these costs are not inherent to the operation of a **HACCP** system, they represent one-third of the total MSSP-based estimates. As indicated earlier in...

... The guidelines are intended to provide the industry with information on how it could implement **HACCP** , not how it must do so.

Costs to importers and to foreign processors that ship...
...of plants that export seafood to the United States and based their costs of implementing **HACCP** on MSSP- generated data on the costs to U.S. plants.

It is important to...

... many of the United States major seafood trading partners are using, or have opted for, **HACCP** programs. For example, the EC will soon require **HACCP** or an equivalent system from over 100 nations that export to it. Consequently, with the current trend toward **HACCP** worldwide, the costs to many foreign processors of implementing **HACCP** may be incurred regardless of whether FDA issued these proposed regulations.
Moreover, in the near...

...S. importers subject to this proposed rule should have little difficulty finding products produced under **HACCP** . FDA specifically invites comment on the estimated costs of the proposed regulations to importers and foreign processors, e.g., whether they are high due to the worldwide move toward **HACCP** or whether they are low due to other factors that have not been considered, and the potential effect on U.S.
consumers of requiring that imports be produced under **HACCP** systems.
The PRIA presumes that most of the cost of compliance of the proposed regulations...

... and FDA invites comment on possible costs associated with them. They include prevention of cross **contamination** by the separation of **food** contact surfaces, storage at 40 deg.F of cooked, ready-to-eat products and products...as a result of adoption of this proposed rule.

The existence of a national, mandatory, **HACCP** -based inspection system for seafood should have a beneficial, although nonquantifiable effect on both the...

... resources in order to respond to the Congress and the media. While public interest in **food** safety is healthy and desirable, the extreme interest in seafood safety, which has manifested itself...

...additional benefit to firms wishing to export seafood to those countries which require federally monitored **HACCP** . The latter two benefits have not been quantified, and FDA requests comments on how this might be done.

The agency followed three steps to quantify the safety benefits of **HACCP** for processors: (1) Identify all significant hazards associated with seafood safety and establish the baseline...

... S. population; (2) estimate the reduction in the number of incidents of each hazard that **HACCP** is expected to accomplish; and (3) quantify the benefit of the reduced illnesses and deaths...

... pollution and seafood safety, consumer perception of seafood safety may overestimate actual risk. In addition, **contamination** scares cause drastic short-term drops in consumer demand for seafood products and undoubtedly contribute...

... has evaluated the possibility that consumers may switch from higher fat flesh protein, such as **meat** and poultry, to seafood. The resulting reduced dietary fat in the diet of the general...affect the ability of small processors to comply with the proposed regulations. First, the basic **HACCP** requirements proposed in subpart A of part 123 deliberately include only the essentials of **HACCP** in order to keep fixed costs to a minimum. Second, FDA is developing considerable guidance in the form of a hazard guide and **model** **HACCP** plans to enable small processors to implement an effective **HACCP** system at the lowest possible cost. Third, FDA is also aware that academia and trade associations are available to assist processors to implement **HACCP** . Finally, for those small processors that have very simple operations requiring few critical control points, an inherent feature of **HACCP** is that it adjusts to the complexity and risks of an operation.

While any closure...

... and take reasonable preventive controls to prevent those hazards from occurring should not be selling **food** in interstate commerce. As described in the preamble, FDA is keenly interested in keeping the costs of implementing **HACCP** to a minimum and is issuing guidance documents and **model** **HACCP** plans to facilitate such implementation.

FDA is specifically requesting comment in areas where costs and...

...on:
(1) The expected cost to retrofit plants as necessary for the proper operation of **HACCP** controls (e.g., enhance refrigerator capacity, water supply changes, etc.).

(2) The cost of taking...

...there will be a cost per plant of $900 to train an employee to manage **HACCP** . This will include the cost of training, travel expenses, and loss of several days of...

...1,000 per plant, initially, with replacement as necessary.

(6) The cost of creating a **HACCP** plan from the guidance provided by FDA. FDA estimated that it will take processors with simpler processes 24 hours of managerial time to adapt the guidance into a **HACCP** plan. FDA estimated that it will take processors with more complex processes 72 hours of managerial time to adapt the guidance into a **HACCP** plan.

(7) FDA requests comment on the recordkeeping burden associated with the proposed sanitation requirements...

...requests specific comments on these areas:

(1) Section 123.10(a)(7), prevention of cross- **contamination** by the separation of **food** -contact surfaces;
(2) Section 123.10(a)(14), storage at 40 deg.F or below...

...comments on both the baseline number of illnesses due to seafood and the likelihood that **HACCP** for processors will reduce those illnesses. The baseline number of illnesses reflects an estimate of...772 80,389 33,035
/1/ Unknown.

Table 2.--Projected Number of Cases Averted Using **HACCP** Approach

	FDA best estimate of the number	Number of cases averted	Number of cases averted...

... benefits (including how to quantify them) as well as other potential benefits such as how **HACCP** will help firms gain better control over their operations, better sanitation and greater efficiencies such...

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List of Subjects

21 CFR Part 123

Fish, Fishery products, Imports, Reporting...

...CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

Therefore, under the Federal **Food** , Drug, and Cosmetic Act and under authority delegated to the Commissioner of **Food** and Drugs, it is proposed that 21 CFR chapter I be amended as follows:
1...

...Definitions.
123.5 Current good manufacturing practice (sanitation).
123.6 Hazard Analysis Critical Control Point (**HACCP**) plan.
123.7 Corrective actions.
123.8 Records.
123.9 Training.
123.10 Sanitation control...

...Integrity

Authority: Secs. 201, 402, 403, 406, 409, 701, 704, 721, 801 of the Federal **Food** , Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 346, 348, 371, 374...

...123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal **Food** , Drug, and Cosmetic Act and in part 110 of this chapter are applicable to such...

...the final container, or to both.

(c) Critical control point means a point in a **food** process where there is a high probability that improper control may cause, allow, or contribute to a hazard in the final **food** .

(d) Critical limit means the maximum or minimum value to which a physical, biological, or...

...aquatic animal life other than birds or mammals.

(f) Fishery product means any edible human **food** product derived in whole or in part from fish, including fish that has been processed...the processing of fish and fishery products.

Sec. 123.6 Hazard Analysis Critical Control Point (**HACCP**) plan.

(a) Every processor and importer shall have and implement a written **HACCP** plan that is specific to:
(1) Each location where fish and fishery products are processed...

... of this section are identical for all fish and fishery products so grouped.

(b) The **HACCP** plan shall:
(1) Identify the safety hazards that are reasonably likely to occur and that...

...controlled for each fish and fishery product, including, as appropriate:
(i) Natural toxins;
(ii) Microbiological **contamination** ;
(iii) Chemical **contamination** ;
(iv) Pesticides;
(v) Drug residues;
(vi) Decomposition;
(vii) Parasites;
(viii) Unapproved direct and indirect **food** and color additives; and
(ix) Physical hazards;
(2) Identify the critical control points for each...

... the operation of critical control points or possible critical limit deviations.

(c) In addition, the **HACCP** plan should:
(1) Identify other consumer hazards not related to the safety of the product...

...of this section.

(d) Failure of a processor or importer to have and implement an **HACCP** plan that complies with this section or to operate in accordance with the requirements of...

... products of that processor or importer adulterated under section 402(a)(4) of the Federal **Food** , Drug, and Cosmetic Act.

Sec. 123.7 Corrective actions.

(a) Any critical limit deviation shall **HACCP**) plan needs to be modified to reduce the risk of recurrence of the deviation; and
(5) Modification when necessary as it applies to the process or **HACCP** plan.
(b) When a processor or importer receives a consumer complaint that may be related...

...accessible location during the period of closure.

(d) All records required by this part, including **HACCP** plans required in Sec. 123.6 and consumer complaints that may be related to a...

... completed a prescribed course of instruction in the application of Hazard Analysis Critical Control Point (**HACCP**) principles to fish and fishery product processing at a program of instruction approved by the **Food** and Drug Administration. At a minimum, this individual shall be responsible for developing and modifying...

...following conditions apply:
(1) Water that directly comes into contact with a product or with **food** contact surfaces, or is used in the manufacture of ice, is derived from a safe...

... are no cross connections between the potable water system and any nonpotable system.

(3) All **food** contact surfaces of plant equipment and utensils, including equipment used for ice production and storage...

... and designed to withstand the environment of its intended use and the action of the **food** , cleaning compounds, and sanitizing agents.

(4) All utensils and surfaces of equipment that contact **food** during processing are cleaned and sanitized with effective cleaning and sanitizing preparations with the following...

...before the beginning of the day's operations.

(5) Gloves and outer garments that contact **food** or **food** contact surfaces are made of an impermeable material and are maintained in a clean and sanitary condition.
(6) Employees' hands, gloves, outer garments, utensils and **food** contact surfaces of equipment that come into contact with waste, the floor, or other insanitary...

...adequately cleaned and sanitized.

(7) Where applicable, employee's hands, gloves, outer garments, utensils and **food** contact surfaces of equipment that come into contact with raw

product shall not contact cooked...

...cleaning and effective sanitizing preparations and single service towels or suitable hand drying devices.

(9) **Food** , **food** contact surfaces, and **food** -packaging materials shall be protected from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, metal fragments, or other chemical or physical **contaminants** .

(10) Toxic compounds shall be identified, held, used, and stored in a manner that protects against **contamination** of **food** , **food** -contact surfaces, or **food** -packaging materials.

(11) **Food** , **food** -contact surfaces, and **food** -packaging materials shall be protected from **contaminants** that may drip, drain, or be drawn into the **food** .

(12) Compressed gases that contact **food** or **food** contact surfaces of equipment shall be filtered or treated in a way that ensures that they will not **contaminate** the **food** with unapproved indirect **food** additives or other chemical, physical, or microbiological **contaminants** .

(13) Unprotected cooked, ready-to-eat fishery products, smoked fishery products, raw molluscan shellfish, and...

...illness, open lesion, including boils, sores, or infected wounds, or any other source of microbial **contamination** by which there is a reasonable possibility that **food** , **food** -contact surfaces, or **food** -packaging materials will become **contaminated** , shall be excluded from any operations that may be expected to result in such **contamination** until the condition is corrected.

(16) Adequate, readily accessible toilet facilities that provide for proper...
...sanitary condition and in good repair.

(17) No pests are in any area of a **food** plant.

(18) The plant is designed to minimize the risk of **contamination** of the **food** , **food** -contact surfaces, and **food** -packaging material.

(b) Each processor shall maintain sanitation control records that document that the steps...

... especially as these relate to hand washing and sanitizing practices and the potential for cross **contamination** , shall be checked and recorded at least every 4 hours during processing.

(2) All utensils and **food** -contact surfaces of equipment shall be inspected immediately after each cleaning and sanitizing operation under...

... of fish or fishery products shall have and implement a Hazard Analysis Critical Control Point (**HACCP**) plan in accordance with Sec. 123.6 that describes how the fish will be prepared...

...the importer.

(b) The importer of fish or fishery products shall have on file the **HACCP** plans of each of its foreign processors.

(c) The importer shall take affirmative steps to...

... that the fish and fishery products that it offers for import were produced under the **HACCP** plan that it has in its possession and subject to the sanitation controls listed in...

...may include, but would not be limited to:

(1) Obtaining from the foreign processor the **HACCP** monitoring records that relate to the specific fish or fishery products being offered for import...

... from a foreign government inspection authority certifying that the firm is operating under a valid **HACCP** plan or certification on a lot-by-lot basis.

(3) Regularly inspecting its suppliers' facilities to ensure that they are being operated in compliance with the applicable **HACCP** plan and Sec. 123.10.
(4) Periodic end-product testing by the importer or a...be functioning and enforceable in its entirety.

(e) Importers should encourage foreign processors to obtain **HACCP** training similar to that required by Sec. 123.9.

Sec. 123.12 Imports--determination of...

... S. importer's place of business, of the importer's Hazard Analysis Critical Control Point (**HACCP**) plan, the foreign processor's **HACCP** plan and sanitation procedures and records associated with the importer's plan that demonstrate that...

...domestic processors.

(3) Evidence that an exporting country has in place and is enforcing an **HACCP** -based regulatory system.

(4) Inspection of foreign processors by FDA or some other organization designated...
...testing.

(b) If assurances do not exist that the product has been produced under an **HACCP** plan and sanitation controls that are equivalent to those required of domestic processors, the product...

... order to meet requirements of subpart A of this part as they apply to microbiological **contamination** , natural toxins, and related hazards, processors shall include in their Hazard Analysis Critical Control Point (**HACCP**) plans how they are controlling the origin of the molluscan shellfish they process.

(b) Processors...

LEGAL PUBLICATIONS:
...75-717 SEC. 402 701 403 303 201 406 409 701 704 721 801 -- Federal **Food** , Drug and Cosmetic Act (Act of 6/25/38...

...Pub. Law 85-929 SEC. 4 -- Federal **Food** , Drug and Cosmetic Act, Amendment (9/6/58)
19940128

17/K/33 (Item 7 from file: 180)
DIALOG(R)File 180:Federal Register

DIALOG Accession Number: 02124182 Supplier Number: 880302439
Availability of Financial Assistance for Research and Development Projects To Strengthen and Develop the U.S. Fishing Industry
Volume: 53 Issue: 59 Page: 10044
CITATION NUMBER: 53 FR 10044
Date: MONDAY, MARCH 28, 1988

TEXT:
...the hakes, ocean pout, skate and mackerel.

b. Develop uniform testing and reporting standards for **contaminants** in fish and shellfish in the Northeast Region.

c. Develop Grade A standards for important...of shellstock by examining

current practices (e.g., depuration) and the extent of shell breakage/ **contamination** .

e. Study application of nucleic acid probes and various immunological techniques to measure and detect... potassium sorbate and lactic acid bacteria to reduce the sodium chloride requirements for inhibition of **botulism** toxin production in smoked fish; analyze the worldwide effect of salmon farming on U.S...

... concern. Shellfish products pose a special health risk because the harvest areas are subject to **contamination** from viruses, pathogenic microorganisms, chemical and other toxic materials; and many are eaten raw. To...

...viruses, but not excluding chemicals.

c. Develop rapid methods to identify the presence of rotovirus **contamination** of shellfish.

d. Conduct a survey to determine the incidence and/or levels of Listeria monocytogenes **contamination** in shellfish.

3. In the interest of maintaining product safety and integrity, the means need...

... geographic origin of fishery products and maintain their identity from point of harvest through the **distribution chain** to the consumer. To address this problem, an evaluation of existing of and potential techniques ...
...collection of casualty data should be incorporated in all proposals.

5. The development of a **model** seafood surveillance program based on Hazard Analysis Critical Control Points (**HACCP**) was initiated in 1987 and focused on the processing of seafood products. To complete this...

... operations. Technical research needed to develop associated methods and tolerances should reflect recommendations identified in **HACCP** industry workshops. Information on ongoing efforts and quality and safety issues identified at **HACCP** workshops on processing operations to date will be provided by NMFS to interested parties.

b. Design, conduct, and document a total economic analysis of the results of a **model** seafood surveillance program as developed and supplied by the National Marine Fisheries Service that is based throughout on the **HACCP** concept. The analysis is to address those controllable processes, from harvesting to retailing, in which...products?
(3) What supporting work activities (be as specific as possible) will be undertaken to **produce** major products, services?
(4) Who will be responsible for carrying out various work activities? (Highlight...
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?